Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 27 Jul. - Aug. - Sep. 2015

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 27thissue of Pharma Web Newsletter for July – Sept 2015. We are happy to announce that one our active member of the trustee, **Dr. V. Ravichandiran,** Director, School of Pharmaceutical Sciences, Vels University, Chennai has assumed the post of **Director, NIPER, Kolkata** likewise **Mr. J. Jayaseelan** Managing Director, M/s. Delvin and our active trust member has been elected as Chairman of IDMA, Tamilnadu.

We are happy to inform our readers that our "Pharma Knowledge and Training Institute" (Finishing School)is conducted a 3rd "Industrial Training programme" for fresh Pharma graduates during September -October2015 for a period of one month on the subject of "QC & QA management". The response to this training programme was enormous for the Pharmacy colleges. In this training programme the total trainees were 60 Pharmacist.

All our Trust members and IDMA Members attended a seminar conducted by Pharmexcil. The main aim of the seminar is to sensitize the pharmaceutical manufacturers in Tamilnadu, the advantage of export of Drugs & Pharmaceuticals to various countries. Hence the lectures delivered by officials form CDSCO and Pharmexcil are published in this issue.

We are publishing the following articles

a. Inspection Observations (Manufacturing Facility) by **Dr. S. Manivannan, Deputy Drugs Controller (ndia), CDSCO, South Zone, Chennai.**

b. Country Oriented Product Positions by **Mr. V. Ravichandran, Director, M/s. Indus Life Sciences Pvt. Ltd. Chennai.**

c. Benefits Available Under MDA & MAI Schemes for Exporters by **Mr. S. Murali Krishna, Deputy Director, Pharmexcil, Hyderabad.**

We have published four Gazette Notifications pertaining to the amendment of Drugs & cosmetics Act & Rules.

a. Diclofenac Sodium Injection need to be manufactured and Marketed in single dose form

b. In the Schedule Y of Drugs & Cosmetics Rules, post marketing surveillance and systemic toxicity study guideline have been introduced in the draft.

c. In the Schedule Y of Drugs & Cosmetics Rules,the audio &video recordings have been made compulsory for recruitment of volunteers.

d. The period of import license for personnel use has been increased to period of six months. Rule 96 the labelling provisions have been incorporated for various items like bold letters for storage of Medicines. Further the existing licenses of pharma companies are valid of one year for export of drugs and pharmaceuticals in case of merge or acquisition of the companies.

Important news items appeared in national News papers on various technical issues are also published in this issue.

Hope this Newsletter will benefit our Pharma professionals.. Any suggestions to improve our news letter are welcome.

With Best Regards

R. Narayanaswamy

Chief Editor

ARTICLES

INSPECTION OBSERVATIONS (Manufacturing Facility)

By

Dr. S. Manivannan,

Deputy Drugs Controller(India), CDSCO, South Zone, Chennai
(Lecture Delivered on 6th August 2015at Hotel Savera, Chennai
Joint Workshop by Pharmexcil & IDMA (TNPSB)

CONTENTS

- **Checklist for Screening the Documents related to COPP (as per CDSCO Guidance Document)**
- **Steps followed in joint inspection of WHO –COPP**
- **Observations related to**
  - Personnel
  - Raw Materials Store
  - Packing Materials Store
  - Finished Goods Store
  - Manufacturing Area
  - Quality Control
  - Quality Assurance
  - Validation
  - Utilities
  - Control Samples
  - Stability Samples.
  - Archival of Records
- **Data Integrity**

CHECKLIST

Checklist for screening the documents related to COPPs.

Name of the firm: M/s .
Date of receipt of application: ----------
Subject: Revalidation/ Grant of COPP.

S.No.	Parameter	Status	Remark
1.	Application from Manufacturer	Yes/No	
2.	Site Master file (as specified under WHO TRS 823)	Yes/No	
3.	Copy of Manufacturing Licence	Yes/No	
4.	List of approved products	Yes/No	
5.	List of products applied for issuance of COPPs	Yes/No	
6.	List of SOPs and STPs	Yes/No	
7.	Stability Data (3 batches, 6 Months)	Yes/No	
	Accelerated	Adequate/ inadequate	
	Real Time	Adequate/ inadequate	

CHECKLIST

8.	List of equipment and Instrument	Yes/No	
9.	List of technical staff, their qualification, experience and approval status	Yes/No	
10.	Manufacturing layout	Yes/No	
11.	Process validation for 3 batches of each product	Yes/No	
12.	Schematic diagram of water system specifying circulation loop and MOC	Yes/No	
13.	Schematic diagram of HVAC system specifying terminal filter configuration	Yes/No	
14.	Export data of last 2 years in case of revalidation	Yes/No	
15.	Product summery sheet	Yes/No	

Opinion: The firm has submitted the documents vide Letter no. ..... dated ..... on scrutiny of the documents, it was observed that all aforesaid documents are in order.
The firm is ready for inspection.

STEPS FOLLOWED IN JOINT INSPECTION OF WHO-COPP

- Applications submitted to SLA / CDSCO.
- Applications scrutinized by CDSCO within 3 weeks time
- If all documents are in order, planning for joint inspection in co-ordination with SLA.
- If any deficiency in documents, query letter raised to the manufacturer.
- After the receipt of required documents based on the query letter – review of documents - planning for joint inspection in co-ordination with SLA.
- Submission of application only to SLA not to CDSCO.
- Requesting postponement of inspections due to some reasons
- Any clarification while submission of an application-Welcome.

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PERSONNEL

- Organogram - Schedule M, Part I, 29.2a of Drugs and Cosmetics Rules 1945.
- Job responsibility - Schedule M, Part 1, 6.4 of Drugs and Cosmetics Rules 1945.
- Resignation of Endorsed technical staff.

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PERSONNEL

Training:

- Training - Written Instructions - All personnel of Production & QC on duties and responsibilities- Schedule M, Part I, 6.6 of Drugs and Cosmetics Rules 1945.
- Training to all personnel whose duties taken into manufacturing areas or in control laboratories including the technical, maintenance and cleaning personal and for other personnel as required. WHO TRS 961, Annex 03, 10.1.
- Newly recruited persons training- on the duties assigned WHO TRS 961, Annex 03, 10.2.

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PERSONNEL

Medical Examination:

- Prior to employment - Medical examination including eye examination, free from tuberculosis, skin and other communicable or contagious diseases. Schedule M, Part I, 7.2 of Drugs and Cosmetics Rules 1945.
- Periodic medical examination- At least once in a year. Schedule M, Part I, 7.2 of Drugs and Cosmetics Rules 1945.

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RAW MATERIALS STORE

- Receiving and dispatch bays should protect materials and products from adverse weather conditions. Schedule M, Part-I, 2.3 of Drugs and Cosmetics Rules 1945.
- Pre-inspection checklist - Schedule M, Part I,10.4 of Drugs and Cosmetics Rules 1945.
- Separate area should be provided for de-dusting activity. Schedule M, Part I, 2.4 of Drugs and Cosmetics Rules 1945.
- Good storage facility

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RAW MATERIALS STORE

- Adequate and separate area for quarantine, under test, approved and rejected area – **Schedule M, Part I, 2.1 & 10.7 of Drugs and Cosmetics Rules 1945.**
- Separate sampling and dispensing areas shall be provided in the ware house - Schedule M, Part –I, 2.5 of Drugs and Cosmetics Rules 1945.
- Sampling tools.
- The area surrounding the LAF station/ sampling booth/ dispensing booth - to be qualified - WHO TRS 961, Annex 5, 4.1.11.

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RAW MATERIALS STORE

- Cleaning record for sampling & dispensing booth and sampling tools to be maintained.
- The differential pressure is not maintained between the change rooms and the room provided with Reverse laminar flow area or room to ensure dust movement between the areas to prevent from contamination and cross contamination. **WHO TRS 961, Annex 05,4.5.1 & Schedule M, Part I, 2.5 of D & Act 1945.**
- Raw Material shall be purchased from approved source. **Schedule M, Part I, 10.3 of Drugs and Cosmetics Rules 1945.**

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RAW MATERIALS STORE

- Precautions are not ensured during sampling and dispensing of light sensitive materials.
- Action in case of rejected materials and time line for disposal of rejected materials.
- Shelf life/ Expiry of the finished formulation should be within the used raw material shelf life. **Schedule M, Part-I, 10.9 of Drugs and Cosmetics Rules 1945.**

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PACKING MATERIALS STORE

- Packing material shall be purchased from approved vendor – **Schedule M, Part I, 10.3 of Drugs and Cosmetics Rules 1945.**
- Segregated areas shall be provided for storing packing materials. **Schedule M, Part I,2.1, 2.8 &13.5 of Drugs and Cosmetics Rules 1945.**
- Specimen of printed material. **Schedule M, Part I, 17.1 (e) of Drugs and Cosmetics Rules 1945.**
- Shipper shall be tested for GSM by using Bursting Strength Apparatus.

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PACKING MATERIALS STORE

- Packing materials - to be issued with reference to the indented quantity.
- Reconciliation of the packing materials shall be done after each batch packing and recorded in the Batch Packing record.

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FINISHED GOODS STORE.

- Thermal Mapping - To identify hot spot.
- Height of Packaging stack.
- No dedicated area for storage of rejected/recalled/returned materials or products. Schedule M, Part I ,2.6 of Drugs and Cosmetics Rules 1945.
- Good distribution practice

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MANUFACTURING AREA

- Dedicated areas shall be provided for sifting, blending and mixing or dust extractors may be fitted to the equipments if placed in a same area. Schedule M, Part IB, 2.1. of Drugs and Cosmetics Rules 1945.
- Filter bags of FBD shall not be used for different products without being washed in between use. Dedicated bags shall be used for highly potent or sensitizing products. Schedule M, Part I B, 2.4 of Drugs and Cosmetics Rules 1945.
- Compressed air used in the coating process (Direct contact of the product) should be filtered. Schedule M, Part I B, 4.1 of Drugs and Cosmetics Rules 1945.

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MANUFACTURING AREA

- The air from the manufacturing areas which is left to the atmosphere shall be filtered to protect the local environment. Schedule M, Part IB, 1.2 of Drugs and Cosmetics Rules 1945.
- Dust extractors shall be installed in compression machine to control facilities and avoid cross contamination. Schedule M, Part IB, 3.1 of Drugs and Cosmetics Rules 1945.
- Drainage shall be provided with traps to prevent back flow. Schedule M, Part I, 1.2 (V) of Drugs and Cosmetics Rules 1945.

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MANUFACTURING AREA

- Hold time studies shall be carried out for bulk stage of the products . The maximum period of storage of the product in the bulk stage shall be validated. Schedule M, Part I D, 3.5 of Drugs and Cosmetics Rules 1945.
- Sinks and drains should not be in Grade A and Grade B areas. Schedule M, Part I A, 2.4 (d) of Drugs and Cosmetics Rules 1945.
- The final change room before entering the aseptic area shall be of same air classification as that of sterile area. Schedule M, pat IA, 3.9 of Drugs and Cosmetics Rules 1945.

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MANUFACTURING AREA

- Microbiological monitoring by settle plate method and /or swabs in the aseptic areas shall be verified daily. Schedule M, Part IA, 4.1 (f) of Drugs and Cosmetics Rules 1945.
- Settle plates should be exposed NLT 2 hours in Grade B, C and D areas. NLT 30 minutes in Grade A areas. Schedule M, Part IA, 4.2 of Drugs and Cosmetics Rules 1945.
- Line Clearance - Checklist - Schedule M, Part I, 8.2.5 of Drugs and Cosmetics Rules 1945.

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MANUFACTURING AREA

Sanitization:

- Validated cleaning procedure . (Schedule M, Part I 9.1 of Drugs and Cosmetics Act 1940).
- Different sanitization agent shall be used in rotation. Schedule M, Part I 9.3/Part I A, 6.2 of Drugs and Cosmetics Rules 1945. (Disinfectants are used more than one type should be employed as per WHO TRS 961, Annex 06, 3.1.)
- Disinfectant programme should include sporicidal agent since many common disinfectants are in-effective against spores. WHO TRS 961, Annex 06, 3.3.
- Fumigation- To reduce microbial contamination. WHO TRS 961, Annex 06, 3.4

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QUALITY CONTROL

- Fume hood cupboards with water drainage system - Schedule L1, 4(m) of Drugs & Cosmetics Rules 1945.
- Eye washers, safety shower - installed - Schedule L1, 6 (c) (i) of Drugs & Cosmetics Rules 1945.
- Separate AHU for Microbiology testing area. Schedule M, Part I , 5.3 of Drugs & Cosmetics Rules 1945.
- Products are licensed as per IP but not tested as per Pharmacopeial method - for want of placebo
- Holding approval in Form-37 and reports not issued under Form-39

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QUALITY CONTROL

- Plastic granules shall also compile with the Pharmacoepial requirements including physico-chemical and biological tests. Schedule M, Part 1-A, Para 11.2
- LAL Test – Incubator
- Sterility test – Product released "under hold" - Schedule M, Part I, 16.6 of Drugs and Cosmetics Rules 1945.

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QUALITY CONTROL

- Standard Biochemical tests shall be performed on sub-cultures to ensure their viability -Schedule L-I, 9 (d) of Drugs and Cosmetics Rules 1945.
- Not more than 5 passage may be prepared for sub cultures. (Schedule L, 9 (c) of Drugs and Cosmetics Rules 1945).
- Residual sample after analysis shall be retained for a period of one year after final report. (Schedule L-I, 16 (a) of Drugs and Cosmetics Rules 1945).

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QUALITY CONTROL

- Raw data on thermal paper – Photocopy preserved - Schedule L-I, 16 (g) of Drugs and Cosmetics Rules 1945).
- Finished product of other companies are used as a reference material of the unit - not recommended. Reference materials should be traceable to agency authorized by Government of India or any other International bodies. Schedule L-I, 8 (a) of Drugs and Cosmetics Rules 1945.
- Register to be maintained for reference and working standard – Schedule L-I, 8(d) of Drugs and Cosmetics Rules 1945.

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QUALITY CONTROL

- Working standard should be verified that it has not deteriorated or decomposed during storage and documented - Schedule L I, 8 (e) of Drugs and Cosmetics Rules 1945.
- Autoclave should be validated for its operation requirements (Sterilization and destruction) and safety- Schedule L –I , 4(l) of Drugs and Cosmetics Rules 1945.
- Bio-burden levels are to be maintained in controlled areas & uncontrolled areas - Schedule L-I, 2(h) of Drugs and Cosmetics Rules 1945.

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QUALITY CONTROL

- Calibration Schedule shall be prepared for all instruments and followed at defined frequency - Schedule L-I, 7(iii) f Drugs and Cosmetics Rules 1945.
- Raw data (Standardization/Weighing/Titration/Printout)
- Growth promotion/other suitable performance tests should be done on all medias on every batch and on every shipment – IP/WHO TRS 961, Annex 02, 5.2.1.
- Prior to packaging and labeling of a given batch of a drug- the samples are to be drawn from the bulk, tested, approved and released by QC - Schedule M, Part I, 13.4 of Drugs and Cosmetics Rules 1945.
- Trend Analysis.

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VALIDATION

- Processing, testing and cleaning validation not performed- Schedule M, Part I, 26 of Drugs and Cosmetics Act 1940.
- Validation test parameters includes accuracy, precision, specificity, limit of detection, limit of quantitation, linearity and robustness. WHO TRS 961, Annex 02, 3.2.
- Filling machine shall be challenged initially then at periodic intervals by simulation trials including sterile media fills. Schedule M, Part IA 7.3 of Drugs and Cosmetics Rules 1945.

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VALIDATION

- Media fill Validation: (WHO TRS 961, Annex 6, 4.23 to 4.26).- Process simulation should be performed on 03 consecutive simulation tests.
- The effectiveness of the sterilization process shall be established initially by biological inactivation studies using microbial spore indicators and then at least once a year by carrying out thermal mapping. (Schedule M, part IA, 7.2 of Drugs and Cosmetics Rules 1945).

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VALIDATION

- Re -Validation at scheduled times is advisable even if no changes had been made in the process - WHO TRS 863, Annex 6. ***(It is because equipment wear may also cause gradual changes, operators change over etc).***
- Process validation – No batch size and pack size mentioned

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QUALITY ASSURANCE

- There is no person/QA authorized to control and issue of the Raw data sheets. Data integrity and security shall be maintained and the data shall not be accessible to any unauthorized person - **Schedule L-I, 15 (c) of Drugs and Cosmetics Act and Rules 1945.**
- QC/QA Personnel - **Schedule M, Part I, 6.3, of Drugs and Cosmetics Rules 1945.**
- Product Recall - SOP for effective recall of products) **Schedule M, Part I, 27.2 of Drugs and Cosmetics Rules 1945.**
- Designated person shall record a final report issued including reconciliation between delivered and recovered quantities of the products. **Schedule M, Part I, 27.2 of Drugs and Cosmetics Rules 1945 & WHO TRS 961, Annex 03, 6.**

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QUALITY ASSURANCE

- Complaints and Adverse Reaction: - **Schedule M, Part IA, 28 of Drugs and Cosmetics Rules 1945 & WHO TRS 961, Annex 03, 5)**
- Annual Product Review
- The COAs are not approved/authorized by QA - **Schedule M, Part. I, 12.2 of Drugs and Cosmetics Act & Rules 1945.**
- Change Control and Deviation.
- **Self Inspection- Schedule M Part-I 29.11a of Drugs and Cosmetics Act & Rules 1945.**

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UTILITIES

AHU

- No Dedicated area for cleaning of filters.
- Preventive Maintenance
- The AHU supplying the areas shall be verified and established at the time of installation and thereafter monitoring at periodic intervals at the stated frequencies as specified in **Schedule M, Part IA, 4.1 of Drugs and Cosmetics Rules 1945.**
- Particulate monitoring in air-6 monthly
- HEPA filter integrity testing-Yearly

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UTILITIES

- Air change rates-6 monthly
- Air pressure differentials-Daily
- Temperature and humidity-Daily
- Microbiological monitoring by settle plates and/or swabs in aseptic areas-Daily at decrease frequency in other areas and also operator glove points
- According to manufacturing load, frequency of monitoring shall be changed.

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UTILITIES

Water System

- Potable water used as a feed water for preparation of purified water shall be tested and conform to the microbiology specification of NMT 500 cfu/ml and absence of individual pathogenic microorganism Escherichia coli, Salmonella, Staphylococcus aureus and Pseudomonas aeruginosa per100 ml sample. (Schedule M, Part IA, 8.1).
- Material of Construction - certificate.
- SOP specifying the sample location, frequency of sampling and testing of different types of water. Schedule M, Part IA, 8.8.

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UTILITIES

- Water for injection storage tank shall have hydrophobic bacterial retention with 0.22 micron vent filters - Schedule M, Part IA, 8.6.
- Steam – contact with the product should be sterile and absence of pathogenic organism - Schedule M, Part IA, 8.9.
- Water under circulation shall be maintained between 70 – 80° C are generally less susceptible to micro organism. - WHO TRS 929 (Annex 3, 6.3)
- Testing of Water for Injection

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UTILITIES

- Water trend to be maintained – (WHO TRS 929 (Annex 3, 7.3)
- Dead leg in pipe work installation greater 1.5 times the branch diameter should be avoided. (WHO TRS 929 (Annex 3,6.5.3)
- Water validation – (three phases). WHO TRS 929 (Annex 3,6.5.3)
- Written procedures for sanitization of storage tank, distribution lines, pumps and related equipments. Record shall be maintained. (Schedule M, Part IA, 8.7).

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CONTROL SAMPLE

- Reference/ retained samples from each batch of manufactured products shall be retained twice the quantity required for complete analysis. Control samples shall be retained till a period of 03 months after expiry of the product. (Schedule M, Pt.I 16.7 of Drugs and Cosmetics Rules 1945).

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STABILITY

- Data from stability studies on at least 3 primary batches– (WHO TRS 953, Annex 2, 2.2)
- Out of the 3 batches 2 should be at least pilot scale batches and third one can be smaller if justified for formulation.
- For API- All 3 batches should be of pilot scale batch.

(Pilot scale is generally at a minimum one tenth that of a full production scale or 100 000 tablets or capsules, whichever is the larger; unless otherwise adequately justified.)

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STABILITY

- At least one batch per year of product manufacture in every strength and every primary packaging type should be included in the stability program. (WHO TRS 953, 2.1.11 & 2.2.12).
- Stability studies of the API should be carried out in a container closure system that is the same as simulates the packaging proposed for storage and distribution/ proposed for marketing. (WHO TRS 953, Annex 2,2.1.4 and 2.2.3).

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- DATA INTEGRITY
- Documentation
- Archival of Records

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COUNTRY ORIENTED PRODUCT POSITIONING (C.O.P.P)

By

Mr. V. Ravichandran,

Director, M/s. Indus Life Sciences Pvt Ltd. Chennai

(Lecture Delivered on 6th August 2015 at Hotel Savera, Chennai
Joint Workshop by Pharmexcil & IDMA (TNPSB)

COUNTRY ORIENTED PRODUCT POSITIONING
(C.O.P.P)

SHARING OUR EXPERIENCE

..... NO THEORY

WHAT IS YOUR BUSINESS MODULE?

GENERICS

CONTRACT MFGR. IN IMPORTER'S BRAND NAME

ONLY TENDER BUSINESS

PRICE SENSITIVE, INSTANT VOLUMES, SHORT LIVED, LOW PROFITS.

BRANDING OF PRODUCTS

PROMOTION INTENSIVE, TAKES TIME, HUGE INVESTMENTS, LONG LASTING, BETTER ROI

A SIMPLE ANALOGY ON POSITIONING
PHOTOCOPIER SHOPS

PHOTOCOPY TAKEN HERE	PHOTOCOPY USING GERMAN TECHNOLOGY	PHOTOCOPY TAKEN IN 30 SECONDS	EVERY 5 PHOTOCOPIES ONE COPY FREE
			
ORDINARY PRODUCT	TECHNOLOGY PRODUCT	CONVENIENT PRODUCT	ECONOMICAL PRODUCT

GENERAL TENDENCY OF EXPORTING COMPANIES

PRODUCTS

- TO OFFER WHAT IS AVAIABLE OR USED IN INDIA OR OTHER MARKETS.

PROMOTION

- TO PROMOTE IN SAME INDICATIONS THAT ARE TRIED AND TESTED IN INDIA.

PRICE

- A GENERAL FEAR THAT HIGH PRICED PRODUCTS CANNOT SELL.

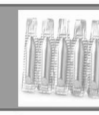
"INSTEAD OF GOING BY THE TREND, WHY NOT CREATE A TREND?"

POSITIONING OF PHARMA PRODUCTS

EFFICACY	MOLECULAR SUPERIORITY (LINAGLIPTIN Vs SITAGLIPTIN)
SAFETY	IN PREGANCY, DIABETICS, HYPERTENSIVES, CHILDREN.
CONVENIENCE	ONCE DAILY (CIPRO – OD), SECNIDAZOLE.
ECONOMY	PRICE DRIVEN
TECHNOLOGY	MOUTH DISSOLVING FORM, TRANSDERMAL,

WHAT DECIDES THE POSITIONING IN OVERSEAS MARKET?

GENERAL DISEASE PATTERN	MALNUTRITION, ANEMIA, MALARIA, HIV, LIFE STYLE DISORDERS, ANXIETY. (INDIA'S TOP COMPANIES SELL ANTACID IRON TONICS IN AFRICA)
PATIENTS PREFERENCE	LIQUID MARKET, SUPPOSITORIES, 100ML PACK, SACHETS, SUGAR FREE LESS SWEET, HOT GEL, COLD GEL ETC
PRESCRIPTION OR OTC	SOME OF THE MULTIVITAMIN ARE BIG IN OTC SEGMENT
PRODUCT RELEVANCE	DOES YOUR PRODUCT MATCH THE ABOVE



COUNTRY ORIENTED PRODUCT POSITIONING

Examples

HAVE YOU POSITIONED YOUR HAEMATINIC FOR COGNITIVE DEVELOPMENT IN CHILDREN?

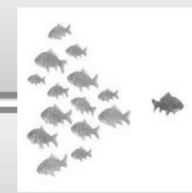
CIPROFLOXACIN RESISTANCE IS CAUSED BY MALARIA TREATMENT. DO YOU HAVE ANOTHER QUINOLONE TO COUNTER THIS?

DO YOU HAVE A CODIENE FREE, ALCOHOL FREE COUGH SYRUP FOR CHILDREN?

EXAMPLES OF COUNTRY ORIENTED PRODUCT POSITIONING

WHEN MOST PEOPLE TAKE 2 x 500mg PARACETAMOL, DO YOU HAVE 1 gm PARA (CONVENIENCE AND ECONOMY)?

WHEN YOUNG GIRLS ARE CONCERNED ABOUT THEIR NAILS, HAIR AND SKIN, DOES YOUR MULTIVITAMIN PROVIDE AN ANSWER?



WHEN DIARRHEA IS SO VIRULENT, DO YOU HAVE A PRODUCT THAT IS SUPERIOR TO METRO, OR PROBIOTIC ADJUVANT?

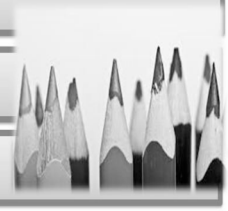
HAVE YOU PROMOTED YOUR HEMATINIC FOR IUGR OR FOR LBW BABIES?

EXAMPLES OF COUNTRY ORIENTED PRODUCT POSITIONING

HAVE YOU PROMOTED YOUR ANTI-HYPERTENSIVE TO PREVENT NEPHRO-TOXICITY?

HAVE YOU LINKED DOSAGE ADVANTAGE TO ECONOMY?

EVERY DEWORMING TREATMENT FOLLOWED BY HEMATINIC.



HAVE YOU TRIED TO LAUNCH FIBER SUPPLEMENT FOR CONSTIPATION?

HAVE YOU MADE THE PROMO IN LOCAL LINGO?

HAVE YOU TRIED TO POSITION YOUR MULTIVITAMIN AS AN ANTIOXIDANT?

SUMMING UP

EVERY MARKET HAS CERTAIN UNIQUE CHARACTERISTIC,
DISEASE PATTERN, PATIENT PREFERENCES
WHICH FORM THE MAIN PART OF PRODUCT POSITIONING.

THERE ARE NO TWO IDENTICAL APPROACHES POSSIBLE TO DIFFERENT MARKETS.

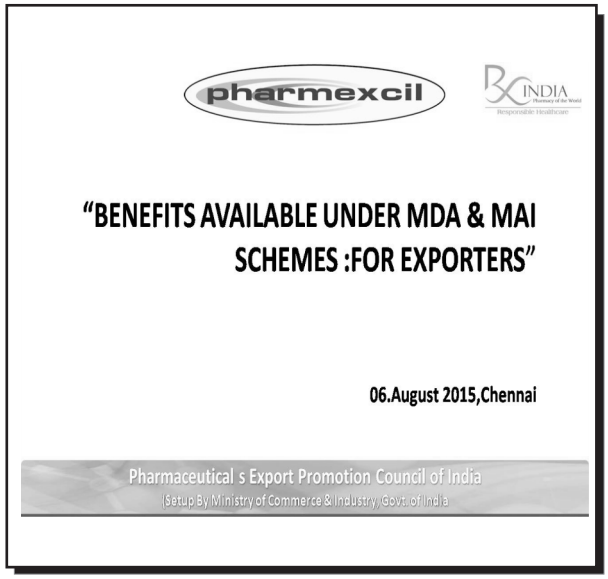
YOUR INDIAN EXPERIENCE IS ONLY A GUIDING FACTOR, BUT THE APPROACH HAS TO BE TAILOR MADE FOR THE COUNTRY.

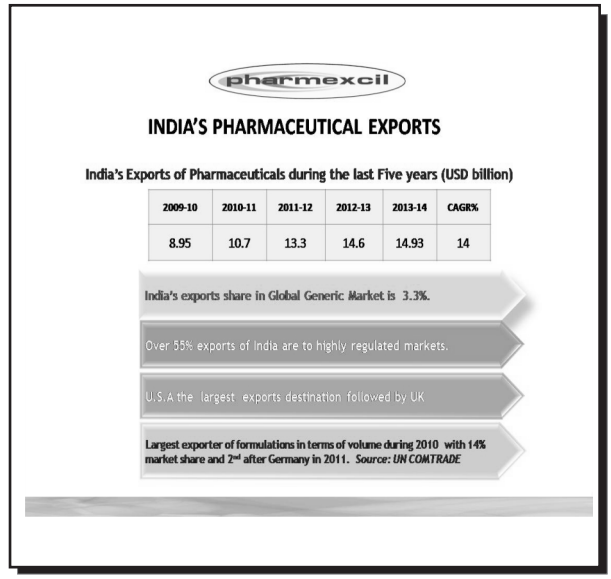
"BENEFITS AVAILABLE UNDER MDA & MAI SCHEMES :FOR EXPORTERS"

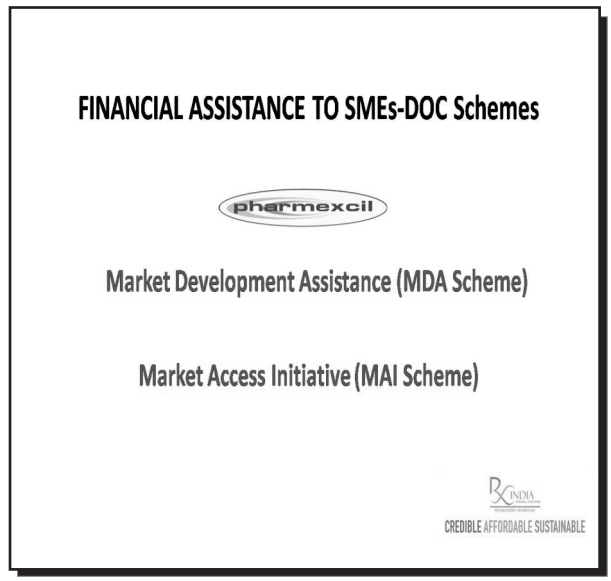
By

Mr. S. Murali Krishna,

Deputy Director, Pharmexcil, Hyderabad
(Lecture Delivered on 6th August 2015 at Hotel Savera, Chennai
Joint Workshop by Pharmexcil & IDMA (TNPSB)







INCENTIVES AVAILABLE FOR EXPORTERS

Some of the most important incentives available to Indian Exporters are:

- Market Development Assistance (MDA) Scheme
- Market Access Initiative (MAI) Scheme

- **The Objectives of the MDA Scheme is basically to assist the SMEs to promote exports of their products and**
- **Explore new markets for their product**
- Focus areas have been identified by the Government of India viz:
  - **Focus CIS**
  - **Focus Africa**
  - **Focus Asean +2 (i.e. Australia & New Zealand.)**
  - **Focus LAC**

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MDA Assistance to Member Companies

- **Exporting companies with an FOB value of exports of up to Rs.30.00 crores in the preceding year are eligible for MDA scheme.**
- **Assistance for Travel (economy excursion class) + built up furnished stall in Focus Areas (Assistance Amount subject to ceiling – Show in separate slide).**
- **Assistance available for participation through Council sponsored activities.**
- **Assistance permissible to one regular employee/director/ partner/proprietor of the company. Exporter of foreign nationality or holding foreign passport will not be eligible.**
- **Intimation application must be received in any of the offices of Pharmexcil with a minimum of 14 days advance notice excluding the date of receipt of application in Pharmexcil & the date of departure from the Country. (Application available for download from our Website.**

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Contd..

- Maximum no. of permissible participations is 5(five) in a financial year i.e. one each in Focus Areas + one in General area.
- Company applying for MDA shall not be under investigation/charged / prosecuted / debarred / black listed under the Foreign Trade Policy of India or any other law relating to export and import business.
- Maximum MDA assistance shall be inclusive of MDA assistance received from all Govt. bodies / EPCs/ FIEO / ITPO etc.
- Member exporters of EPCs etc would also be eligible for MDA assistance for participation in events organized by ITPO abroad. Their applications / claims would be routed / reimbursed through the concerned EPC etc.
- A maximum of 3(three) participations in a particular trade fair / exhibition would be eligible for MDA assistance.

7

LEVEL OF ASSISTANCE UNDER MDA SCHEME

MDA Amount Ceilings & Visits in each areas permitted			
S. No.	Area / Sector	No. of Visits	Maximum financial Ceiling per event
1	Focus LAC	1	Rs.2,50,000
2	Focus Africa (including WANA Countries)	1	Rs.2,00,000
3	Focus CIS	1	Rs.2,00,000
4	Focus ASEAN + 2	1	Rs.2,00,000
5	General Areas	1	Rs. 1,50,000
	Total Visits	5	

8

MDA Assistance to Member Companies

- Council organises Delegations and Trade Fairs across the globe giving Small and medium scale an opportunity to showcase their products and to promote exports. Council supports members by part financial assistance in the form of reimbursement on completion of the visit/participation:

- Financial Assistance extended by Council to member companies during the last three years: (in INR Crores)

  ❑2012-13: Rs.1,40,18,538
  ❑2013-14: Rs.2,43,08,743
  ❑2014-15: Rs.2,60,00,000

CREDIBLE AFFORDABLE SUSTAINABLE

FACILTATING MEMBER COMPANIES

- During the year 2013-14 Council participated in about 21 events worldwide under MDA & MAI Activities

❑Total number of Events under MDA & MAI : **21 events**
❑Number of Countries Covered : **26 countries**
❑Company Participation : **899 companies**

Council always give first preference to SMEs in all our events

CREDIBLE AFFORDABLE SUSTAINABLE

FACILTATING MEMBER COMPANIES

- During the year 2014-15 Council participated in about 22 events worldwide under MDA & MAI Activities.

❑Total number of Events under MDA & MAI : **22 events**
❑Number of Countries Covered : **22 countries**
❑Company Participation : **1181 companies**

CREDIBLE AFFORDABLE SUSTAINABLE

ASSISTANCE THROUGH MAI SCHEME

- Scope of MAI Scheme
  - Marketing Projects Abroad(focus product or focus country)
  - Capacity Building
  - Support for Statutory Compliances
  - Studies
  - Project Development
  - Miscellaneous

12

ASSISTANCE THROUGH MAI SCHEME

- Council encourages member companies to register their products as many countries as possible and promotes exports to these countries. Exporters are given financial support for every product registered with FDA overseas by reimbursing 50% of the fees paid to FDA.
- The maximum limit of reimbursement is Rs.50 lakhs per company per year for such product registrations.
- Financial assistance extended to member companies during the last three years :(INR Crores)
  - ❑2012-13: Rs.2,70,77,445
  - ❑2013-14: Rs.3,82,54,632
  - ❑2014-15: Rs.2,33,25,566

CREDIBLE AFFORDABLE SUSTAINABLE

ASSISTANCE THROUGH MAI SCHEME

- Reimbursement of 50% of DMF, ANDA fees paid foreign regulatory authorities
- Reimbursement of 50% (for companies with less than Rs.250 crores investment on Plant & Machinery) and 25% (for companies with more than Rs.250 crores investment on P& M) expenses incurred on Bioequivalence tests conducted, subject to some prescribed conditions.(Requested DoC for clarification on soe points)
- Reimbursement of 50% of Patents filing expenses , provided the patent is owned and assigned at Indian soil and subject to a minimum 75% ownership is with Indian public/promoters
- Reimbursement of costs associated with travel and stay of visiting inspectors of foreign regulatory authorities for inspection of facilities, subject to a ceiling of Rs.75,000/- (Rs.1.00 lakh in case of American continents) per official. (Inspection fees not included)-More than one visit from the same country, clarification is to be take with DoC)

(All reimbursements not exceeding Rs 50.00 Lakhs per annum).

AYUSH CELL & AYUSH ADVISORY GROUP IN PHARMEXCIL

- Ayush Cell is administered by Ayush Advisory Group with representation from large, medium and small scale industry stakeholders of herbal and ayush segments.
- Recently, the Ayush Cell has successfully organised International Buyer Seller Meet with participating from about 55 Overseas Delegates from 20 countries during 6th World Ayurveda Congress and about 150 Indian delegates had one to one Business meetings during 7th & 8th November 2014

CREDIBLE AFFORDABLE SUSTAINABLE

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th July, 2015

G.S.R. 558(E).—Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare vide number G.S.R. 503(E), dated the 14th July, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 14th July, 2014;

And, whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in rule 105, in sub-rule (2),

(i) in the second proviso, for the words "Provided also that", the words "Provided further that" shall be substituted;

(ii) in the third proviso, for the words "Provided further that", the words "Provided also that" shall be substituted;

(iii) after the third proviso, the following proviso shall be inserted namely:—

"Provided also that Diclofenac injection for human use shall be in single unit dose pack only." ;

[F. No.18-6/2013-DC/DFQC]

K. L. SHARMA, Jt. Secy.

Note.- The principal rules were published in the Gazette of India, *vide* notification No. F.28-10/45-H (1), dated the 21st December, 1945 and last amended *vide* notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide G.S.R. 390 (E), dated the 18th May, 2015.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th July, 2015

G.S.R. 559(E).—The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, shall be considered by the Central Goverument.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110011.

Draft rules

1. (1) These rules may be called the Drugs and Cosmetics (Fourth Amendment) Rules, 2015.

   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule Y,—

   (A) for paragraph "**(2) Post Marketing Surveillance**" and clause (i) relating thereto, as published in Part II, Section 3, Sub-section (i) of the Gazette of India, dated the 20th January, 2005, at page 63, the following shall be substituted, namely:—

   "**4. Post Marketing Surveillance.-**

   (i) The applicant shall have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant in the country.

   (ia) The system shall be managed by qualified and trained personnel and the officer in-charge of collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

   (ib) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.

   (ic) The applicant shall furnish Periodic Safety Update Reports in order to-

   (a) report all relevant new information from appropriate sources;

   (b) relate the data to patient exposure ;

   (c) summarise the market authorisation status in different countries and any significant variations related to safety; and

   (d) indicate whether changes shall be made to product information in order to optimise the use of product.";

   (B) in Appendix III, in paragraph 1.8, in the table,—

   (i) under the heading 'Systemic Toxicity Studies', for sub-heading "Oral or Parenteral or Transdermal" and entries relating thereto, the following shall be substituted, namely:-

"Oral, or parenteral or transdermal	Single dose or several doses in one day, Upto 1 wk	I,II,III	2sp, 2wks
	>1 wk but upto 2 wks	I,II,III	2sp; 2wks
	Upto 2 wks	Marketing permission	2 sp; 4 wks
	>2 wks but upto 4 wks	I, II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; 12 wks
	> 4 wks but upto 12 wks	I,II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; 24 wks
	> 12 wks but upto 24 wks	I,II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; Rodent 24 wks, non-rodent 36 wks
	> 24 wks	I,II,III	2 sp; Rodent 24 wks, non-rodent 36 wks
		Marketing permission	2 sp; Rodent 24 wks, non-rodent 36 wks";

   (ii) under the heading "Male Fertility Study", for entries there under, the entries "Phase III in male volunteers or patients" shall be substituted.

[F. No. X. 11014/12/2011-DFQC]

K. L. SHARMA, Jt. Secy.

Note.- The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H (1), dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 390(E) dated the 18th May, 2015.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st July, 2015

G.S.R. 611(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 364(E), dated the 7th June, 2013, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 7th June, 2013, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 07th June, 2013;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Fifth Amendment) Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule Y,—

(i) in paragraph 2 under the heading "CLINICAL TRIAL", in sub-paragraph (4) relating to "Informed Consent", after clause (iii), the following shall be inserted, namely:—

"(iv) An audio - video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record;

Provided that in case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.";

(ii) in APPENDIX V, under the heading "INFORMED CONSENT", in sub-heading 1.1 relating to "Essential Elements", for serial number 14 and the entries relating thereto, the following serial numbers and entries shall be substituted, namely:—

"14. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

15. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

16. Any other pertinent information.".

[F. No.X.11014/1/2012-DFQC]

NIKUNJA BIHARI DHAL, Jt. Secy.

Note : The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H (1) dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 390(E) dated the 18th May, 2015.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 20th August, 2015

G.S.R. 648(E).—The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, shall be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

Draft rules.

1. (1) These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2015.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 36, in the second proviso, after clause (iii), the following clause shall be inserted, namely:-

"(iv) the permit is granted for a period of six months or in special circumstances for such period beyond six months as may be specified.".

3. In the said rules, in rule 96, in sub-rule (1),-

(A) in clause (i),-

(a) the brackets and letter "(A)" shall be omitted;
(b) sub-clause (c) shall be omitted;

(B) in the proviso to clause (iii), the words "and to a preparation included in the National Formulary of India" shall be omitted;

(C) after clause (xii), the following clause shall be inserted, namely:-
"(xiii) the conditions of storage with specific temperature range in thick and bold letters.".

4. In the said rules, in Schedule A,-

(a) in Form 12-B,-
(i) in paragraph 3, after the words "six months", the words "or for such period beyond six months as may be specified", shall be inserted;
(ii) after paragraph 3, the following paragraph shall be inserted, namely:-
"4. The permit shall be valid from _____ to _____.";

(b) in Forms 25, 25-A, 25-F, 28, 28-A, 28-B, 28-D and 28-DA, under the conditions of licence, after condition 4, the following provisos shall be inserted, namely:-
"Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:
Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.";

(c) in Form 25-B, under the conditions of licence, after condition 5, the following provisos shall be inserted, namely:-

"Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:

Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.";

(d) in Form 25-C, under the conditions of licence, after condition 3, the following provisos shall be inserted, namely:-

"Provided that where the licensee is an exporter and the company of such licensee is in the process of merger or acquisition, the licence shall be valid for the purpose of export only, for a period of one year from the date of such merger or acquisition:

Provided further that the period of one year may be extended in special circumstances on the recommendation of the Licensing Authority defined under clause (b) of rule 21.";

5. In the said rules, in Schedule K, after serial number 35 and the entries relating thereto, the following serial number and entries shall be inserted, namely:-

Class of Drugs	Extent and Conditions of Exemption
"36. Sterile solutions intended for parenteral administration with 100 ml. in one container for single use manufactured for export by the hundred per cent export oriented units.	The provisions of Chapter IV of the Act and rules thereunder which require them to obtain a licence in Form 28D or 28DA from the Central Licence Approving Authority subject to the condition that such drugs have been manufactured for export purpose under a licence granted by the State Licensing Authority.".

[F.No. X.11014/2/2015-DFQC]

K. L. SHARMA, Jt. Secy.

Note.-The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number G.S.R.611(E) dated the 31st July, 2015.

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This issue of Pharma Web is also available online at the Trust website www.pictrust.com

INFORMATION

M. Pharm & Pharm D Scholarships 2014-15 awarded by TNPSWT

Profile of 3rdRank Projects

PHARMACEUTICS

Name: Ms.R.Nithya

Project Title: "Folate and transferring conjugated solid lipid nanoparticle loaded Paclitaxel for enhanced bioavailability and targeting cancer cell

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Mr.S.M.HabiburRahman

PHARMACEUTICAL CHEMISTRY

Name: Ms.S.Saranya

Project Title: Design, Synthesis, Characterization and Biological evaluation of some new heterocyclic derivatives as antitubercular agents

College: Madras Medical College, Chennai

Guide's Name: Dr.A.Jerald Suresh

PHARMACEUTICAL ANALYSIS

Name: Ms.Manasi K Patel

Project Title: Stability indicating analytical method for the identification and quantification of Avanafil API from its degradation products by RP-HPLC method

College: JSS College of Pharmacy,Ooty

Guide's Name: Mr.B.Babu

PHARMACOLOGY

Name: Mr. Mohamed Thoraic C

Project Title: Evaluation of Anti-Aging and Immunomodulatory potential of Carnosine extracted from Gallus Gallus Domesticus (Chicken)

College: Madras Medical College, Chennai

Guide's Name: Mrs M Sakthi Abirami

PHARMACOGNOSY

Name: Ms. S.Z. Mushahida Parveen

Project Title: Pharmacognostical, Phytochemical and Anti- Arthritic activity of bark of Erythrinastricta Roxb

College: Madras Medical College, Chennai

Guide's Name: Dr. N.Jayshree

PHARMACY PRACTICE

Name: Mr. Pribin Thomas

Project Title: Evaluation of the Rationality and cost comparison of fixed dose combinations of antibiotics in a tertiary care hospital

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Mr. V.Shivashankar

PHARM D – PHARMACY PRACTICE

Name: Mr.Anna John Viany, Mr. Parul Elsa Thomas, Mr. Vivek Thomas John

Project Title: Assessment risk factors with cerebral ischemic stroke in diabetes, dyslipidemic and hypertensive patients

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Mr. A.Justin

PHARM D- CLINICAL PHARMACY

Name: Ms. JemyRajan, Ms. Mahima Thankam Koshy, Ms. Stefin Mary Mathew

Project Title: Optimization of insulin dose in patients with type 2 diabetes mellitus using response surface methodology

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr.D. Raja

CONGRATULATIONS

We are pleased to inform all our reader that **Dr. V. Ravichandiran,** Director, School of Pharmaceutical Sciences,Vels University assumed charge of the prestigious post of Director, National Institute of Pharmaceutical Education and Research (NIPER) at Kolkata in the month of July 2015.

He is one of the very active Governing Body Members of our Trust. He is Vice President of IPA, TN Branch and Tamilnadu Pharmacy Council. We congratulate him for his elevation to the prestigious post.

We wish him all success.

J Jayaseelan, Managing Director,
M/s. Delvin Formulations elected chairman of Tamil Nadu IDMA

The Tamil Nadu state board of the Indian Drug Manufacturers Association (TN IDMA) has elected **Mr. J. Jayaseelan,** Managing Director of Delvin Formulations, a conglomerate of diverse range of pharmaceutical manufacturing and marketing companies in Chennai, as its Chairman.

He is currently the secretary of IPA, Tamil Nadu besides holding positions such as chairman of public relations of IDMA and secretary of the industrial division of IPA. He was one of the key members who were instrumental in organizing the 64th Indian Pharmaceutical Congress (IPC) in Chennai in 2012.

As the chairman of the state board, Mr. J. Jayaseelan wants to take forward the proposal mooted by TN IDMA last year with regard to setting up of a pharma park nearin Chennai, for the expansion of pharmaceutical industry in the state. Similarly, he plans to mobilise support of all pharma industry organizations to request the state government to frame a separate pharma policy for Tamil Nadu on the lines of the pharma policy of Gujarat government.

The state IDMA will provide all support to the pharma SMEs in Tamil Nadu and Puducherry by way of continuous training programmes. It also wants to promote cluster concepts among the industry leaders, he said while replying to a query.

Mr. J. Jayaseelan started his career as an entrepreneur in the year 2000 and gradually raised a group of companies worth Rs. 500 crore in a period of ten years. He has wide industry contacts across India, USA and in 40 semi regulated markets.

He has promoted CRO, API facility and formulation facility in Chennai which are all US FDA approved facilities.

He is an active secretary of IPA TN Branch as well as Joint Treasurer of our Trust. We congratulate him for his elevation as Chairman of IDMA, TN Branch.

NEWS

Delhi High Court Upholds US-based BMS' Patent for Cancer Drug Dasatinib

The Delhi High Court has upheld the patent of US-based Bristol Myers Squibs (BMS) for Dasatinib, dashing the hopes of a local company to sell a generic version of the cancer drug and providing some relief to multinational drugmakers who are up in arms against India's patent laws.

Justice Manmohan of the high court rejected Mumbai-based BDR Pharmaceuticals plea, which challenged the patent citing a provision in the Indian Patent Act that disallows evergreening of drugs. Evergreening is a practice by which holders of patents that are nearing expiry try to extend royalties, though steps such as taking new patents.

The local company argued also that the high price charged by BMS was against public interest. Dasatinib is used in the treatment of chronic myeloid leukaemia.

In India, a month's dose of the drug costs about 1 lakh. BDR had applied for a compulsory licence for the drug in March and said it would sell a month's drug at Rs. 8,100. Compulsory license is a provision under the Trade Related Intellectual Property Rights agreement wherein a government can allow a company to manufacture and sell patented drugs without the consent of the innovator.

BMS could not be reached for a comment. BDR managing director Dharmesh Shah said the company has yet to review the order copy.

The Indian Patent Office had earlier in 2013 rejected the company's demand for a compulsory licence as it did not follow the procedures for obtaining a voluntary licence from the patent holder.

India's patent laws have become a major irritant for multinational pharma companies who were flummoxed by India granting a compulsory licence for German drugmaker Bayer's kidney cancer drug Sofosbuvir and the Supreme Court's decision of rejecting the patent for Novartis' cancer drug Glivec.

Source: *The Economic Times, 7th July 2015*

Source: *The Times of India, 8th July 2015*

Drugs for Pain, Diabetes to Cost up to 40% Less

In welcome relief to thousands of patients, the drug pricing regulator has decided to cut prices of widely used drugs used to treat diabetes, infections, pain and digestive disorders.

The price changes, in the range of 5-40%will be applicable with immediate effect. The move is expected to impact multinational drugmakers like Abbott and GSK and domestic firms including Lupin, Cadila, Ipca and Sun Pharma. The drug price regulator issued the order to fix the prices of 39 formulations.

The government looks determined to keep medicine prices low brushing aside the pharmaceutical industry's concerns over its unviability impacting new launches and competition in the market. The drug price regulator has capped prices of 39 more medicines including commonly used antidiabetic drugs, antibiotics as well as new brands of analgesics like paracetamol and diclofenac.

The price reduction came soon after the industry released data showing a 75% decline in new drug launches since 2013, when the new drug price regulation came into place. A report released by IMS health, a leading market research agency along with pharmaceutical industry associations, also showed that brands under government price control are exiting the market due to squeezing margins.

However, the National Pharmaceutical Pricing Authority (NPPA), which regulates prices of medicines sold in India, has refused to buy into such arguments.

In its latest order, NPPA has brought under price control various new brands of existing medicines. Besides, it has also included some price-controlled medicines which have been launched with different combinations.

Though the industry accuse the regulator of surpassing its purview beyond the drug pricing policy public health experts argue that companies often use such routes like launch of new brands and combination drugs to circumvent price control.

Meanwhile, the Supreme Court has asked the government to re-examine its pricing policy for essential medicines after some public health groups challenged some of its provisions. One of the major points of contentions is the formula based on which prices of essential medicines are fixed by the regulator.

Under the existing pharmaceutical policy, the regulator caps prices of 348 essential medicines or 652 packs based on simple average of all medicines in a particular therapeutic segment with at least 1% market share. Public health groups argue that this market driven pricing mechanism fails to address the concern that was initially raised by them and supported by the court.

The National Pharmaceutical pricing Policy 2013, has its roots in the SC order which directed the government to ensure that all essential medicines are affordable.

Source: *The Times of India, 17th July 2015*

12 years off Drugs, Teen's HIV in Check

An 18-year-old French teen born with HIV has had her infection under control and nearly undetectable despite stopping treatment 12 years ago -an unprecedented remission, doctors are saying.

The teen might have some form of natural resistance to HIV that hasn't yet been discovered. But her case revives hope that early, aggressive treatment can limit how strongly the virus takes hold, and perhaps in rare cases, let people control it without lifelong drugs.

A few years ago, doctors reported a similar case: a Mississippi girl who kept HIV in check for 27 months without treatment. But then her virus rebounded, dashing hopes that early treatment might have cured her.

At least a dozen adults have had remissions for a median of 10 years after stopping HIV medicines, but the new French case is said to be the first long-lasting one that started in childhood. The case was described on Monday at an International AIDS Society conference in Vancouver British Columbia by DrAsierSaez-Cirion of the Pasteur Institute in Paris. The teen lives in Paris and her identity was not revealed.

“This is an exciting story,“ but it is unknown if the remission will last, said Francoise Barre-Sinoussi, a scientist at the Pasteur Institute and a co-discoverer of HIV . “This case is clearly additional evidence of the powerful benefit of starting treatment as soon as possible,“ she said.

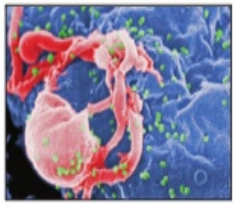
Most HIV-infected moms in the US get AIDS medicines during pregnancy, which greatly cuts the chances of them passing the virus to their babies. The French teen's mother did not have her HIV under control in pregnancy, and doctors think her daughter was infected before or during birth.

Doctors gave the baby an HIV drug -zidovudine, or AZT -for six weeks, which was the standard of care at that time. Tests then showed she still had high levels of HIV in her blood, so she was given a more powerful fourdrug combination.

She stayed on treatment until she was 6 after which the doctors lost contact with her. When she came back a year later, her mother said she had stopped giving the girl HIV drugs. The doctors could not find HIV in her blood and decided not to resume the treatment.

Except for one brief rise when she was 11 that resolved on its own, her virus has remained below a detection threshold ever since, although doctors can still find some at extremely low levels when they look with very sensitive tests.

“This girl is in remission of infection but she is infected and not cured“, Saez-Cirion said.She doesn't have any of the gene variants or other biomarkers that are known to give natural control or protection from HIV infection, and was not able to suppress the virus on her own before getting the powerful drug combo, which suggested early treatment is responsible for the remission, he said.



The teen might have some form of natural resistance to HIV that hasn't yet been discovered. The case suggests early, aggressive therapy can help fight the virus

Source: *The Times of India, 17th July 2015*

Brain Implant to Help Deliver Drugs Via Remote Control

Researchers have developed a new wireless device, the width of a human hair that can be implanted in the brain and activated by remote control to deliver drugs.

The technology, demonstrated for the first time in mice, one day may be used to treat pain, depression, epilepsy and other neurological disorders in people by targeting therapies to specific brain circuits, said researchers at Washington University School of Medicine in St Louis and the University of Illinois at Urbana-Champaign. They added that with one of these devices imp8lanted, we could theoretically deliver a drug to a specific brain region and activate it with light. This approach could deliver therapies that are much more targeted but have fewer side effects.

The new devices may help people with neurological disorders and other problems.

"In the future, it should be possible to manufacture therapeutic drugs that could be activated with light," said co-principal investigator Michael R Bruchas, associate professor of anesthesiology and neurobiology at of Washington University. Previous attempts to deliver drugs or other agents to experimental animals have required the animals to be tethered to pumps and tubes that restricted their movement. But the new devices were built with four chambers to carry drugs directly into the brain. By activating brain cells with drugs and with light, the scientists are getting an unprecedented look at the inner workings of the brain.

Source: *The Times of India, 18th July 2015*

Self-Medication Trap: TN Tops in Deaths Due to Drug Overdose

Tamil Nadu seems to be taking the saying `physician, heal thyself ' to an all new level, with an increasing number of people self-medicating and killing themselves in the process.

With 205 deaths in 2014, the state recorded the highest number of deaths related to drug overdose, according to the National Crime Records Bureau. At least 80% of them were caused by popping pills intended to heal.

Police officials said investigations into these cases revealed that most of the victims were oblivious to the danger of overdosing on drugs, and were looking to cure themselves.

“They didn't overdose because they wanted to take their lives, but to relieve themselves of pain or other health problems for which they were already on medication,“ said a senior police official. He said hospitals refer such cases to police, suspecting them to be suicide cases. “But during investigation, we find that these people unwittingly took the drugs, many of which were sold over the counter.“

The use of illegal and psychotropic substances have actually fallen in the state.

While Tamil Nadu topped the list of deaths due to drug overdose, Punjab recorded the second highest number of deaths caused by drug overdose (186), followed by Haryana (76). Deaths are usually associated with prolonged and frequent use of prescription drugs used to treat conditions like sleeplessness stress, anxiety and pain. “We have no control over the drugs we take”, said surgical gastroenterologist Dr R Surendran. “One, there are pharmacies without qualified pharmacists which generously prescribe pills. And two, people take drugs just based on the effects they have seen on someone else, without realizing the complications“.

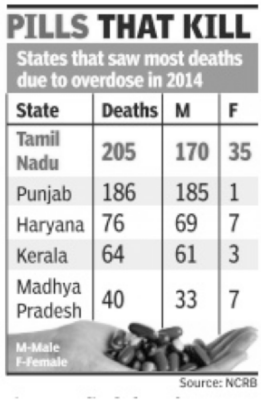
He said while over dose of painkillers and antibiotics can affect the kidney, some drugs take a toll on the liver. “People who a ready have a compromised kidney or a liver because o diabetes, hypertension or other conditions are the most susceptible,“ said the doctor.

In some cases, the drugs are mixed with other medication or alcohol, making them even more deadly. “You don't necessarily have to take over a dozen pills to overdose Some are so potent that even two pills can lead to complications, especially if the per son is allergic to it,“ said DrRaghunandhan, head of community medicine and works with the toxicology department at Madras Medical College. While allergic reactions can result in immediate death, long-term overdose of prescription drugs can trigger acute problems in people with chronic ailments.

“People expect a pill for almost anything. We need a prescription monitoring system to prevent this doctor shopping, and better patient education about the risks of prescription drugs,“ said DrRaghunandhan.

Experts say one of the reasons why Tamil Nadu topped the list of deaths due to drug overdose could be because of better reporting.“It's actually surprising that Tamil Nadu tops the list because the incidence of drug addiction and intake is much higher in Punjab,“ said DrAnithaRao, director, medical services at the de-addiction centre attached to TTK Ranganathan Hospital.

Experts cautioned that people also need to be made aware that some prescription drugs are highly addictive. “Instead, there are nondrug alternatives, such as counseling or physiotherapy, that may work better for patients,“ said DrRaghunandhan. “Popping pills is not always the only recourse.“



People expect a pill for anything. We need a prescription monitoring system to prevent this doctor shopping, and better patient education about the risks of prescription drugs, said Dr Raghunandhan. Experts say better reporting is one reason why TN topped the list

Source: *The Times of India, 22nd July 2015*

Aurobindo Pharma Under FDA Lens

Hyderabad-based Aurobindo Pharma is the latest addition to an expanding list of Indian drug firms that have come under the scanner of the US health regulator.

During a recent week-long inspection at its Unit 12 manufacturing site, the Food and Drug Administration raised issues related to the quality management systems of the company, a person with direct knowledge of the scrutiny said.

The inspection that concluded last week had found shortcomings in the facility management procedures of the site besides issues with handling of investigation processes. "However, the company has taken up the task of addressing the issues and will file the remediation report with the FDA," this person said on the condition of anonymity as he is not authorised to speak on the subject.

Aurobindo's Unit 12 is used mainly to export the US products like tazobactam and piperacilin, an anti-bacterial injection.

An email sent to the investor relations representative of the company on Monday for

details on the inspection went unanswered. An Aurobindo Pharma spokesperson declined to comment when contacted over the phone.

Though no disruption of supply is expected in the short term because of the observations, the FDA is said to have directed the company to furnish detailed plans for correction of the anomalies. The new observations come just two years after the US drug regulator lifted an import ban imposed on one of Aurobindo's important manufacturing facilities, named in the industry circles as Unit 6. The FDA had also inspected the Unit 6 facility recently and found that the company had addressed the issues which were "minor" in nature, a source said. In the last couple of years, Indian generic drug makers have come under intense scrutiny of the US FDA for non-compliance of good manufacturing practices. Since 2013, the FDA has issued import ban on 22 Indian drug makers, mainly owing to deviations in their manufacturing practices. The US remains an important market for leading Indian generic makers, contributing as much as half their export revenue.

For Aurobindo, it is no different. For the quarter ended March 31, 2015, the company reported a net profit of Rs 403 crore on net sales of Rs 3,142 crore, over 50% of which came from US exports. Issues related to manufacturing quality of drugs have dogged the global drug industry alike, cutting across innovators as well as generic makers.

A June 2015, a report by Boston Consulting Group focusing on the quality of manufacturing in the bio-pharma industry and its possible solutions, noted that from 2010 through 2014, 11 of the top 15 biopharmaceutical companies received warning letters from the US FDA. It further added that the manufacturing quality levels in the drug industry remained well below those in other industries, such as semiconductor manufacturing and aerospace.

"Such problems can come at a steep price - in some cases hundreds of millions of dollars in lost revenue, remediation costs that can run in the tens of millions of dollars, and a big hit to the company's reputation," BCG said in its report. The report highlighted that quality programmes typically reside exclusively within the quality function and fail to address organisation-wide processes.

Source: *The Economic Times, 22nd July 2015*

Gavis Will Give Indian Pharma Co Access to Specialty Drugs, Boost US Biz

The country's third largest drug company Lupin is buying privately-held US generics company GAVIS Pharmaceuticals and Novel Laboratories (Gavis) for $880 million to strengthen its presence in its largest market, the US. It will also give Lupin access to a host of specialty generic drugs and niche products, mainly in dermatology, gastro-intestinal and injectables. Specialty and complex generics is the hottest section of the pharma market globally, commanding steep valuations, with even Big Pharma chasing them.

At over 9x market capitalization sales, the deal is the biggest pharma overseas acquisition by a domestic company in recent years. Gavis had sales of $96 million in FY14 and over 250 employees. The deal, which is cash-free and debt-free, widens the company's pipeline in dermatology and controlled substance products. It will be funded by a bridge loan, with Rs 10 crore from existing cash reserves deployed for it.

Justifying the steep valuation, Lupin CEO Vinita Gupta said the “scale and calibre of Gavis pipeline“ needs to viewed, and complex generics are attractive in the US, with even higher multiples. Gavis' capabilities and pipeline are an “excellent complement to Lupin. The acquisition is expected to be accretive to the earnings from the first full year of operations. In addition to the compelling strategic fit, there is a strong cultural fit between Gavis and

Lupin's entrepreneurial spirit and values".

The deal is expected to triple Gavis' revenues by 2018 from $96 million last year. The company currently has 66 ANDA filings pending approvals in the US and 65 products under development. The pending filings have an addressable market value of $9 billion, while it has filed 25 Para IVs and eight first-to-file products, which will give it market exclusivity for some time.

"The deal significantly boosts Lupin's existing business and growth prospects over the next few years," Gupta added. "It puts us in a tremendous position from the pipeline perspective to capitalize on generics opportunities."

The deal follows three other acquisitions this year by Lupin aimed at building its presence in Latin America and Russia.

The combined company will have a portfolio of 101 inmarket products, 164 cumulative filings pending approval and a deep pipeline of products under development for the US.

TOP PHARMA DEALS IN INDIA

Target	Acquirer	Deal size ($bn)	Year
Ranbaxy	Daiichi	4.6	2008
Ranbaxy	Sun Pharma	4	2014
Piramal (Domestic)	Abbott	3.7	2010
Agila Specialties	Mylan	1.8	2013
Gavis	Lupin	0.9	2015
M&As Are Hot In Generics Globally			
Allergan	Actavis	71	2014
Hospira	Pfizer	17	2015
Par Pharma	Endo	8	2015

Source: *The Times of India, 24th July 2015*

Drug Cos Eye `Superhuman' Genes

Steven Pete can put his hand on a hot stove or step on a piece of glass and not feel a thing, all because of a quirk in his genes. Only a few dozen people in the world share Pete's congenital insensitivity to pain. Drug companies see riches in his rare mutation. They also have their eye on people like Timothy Dreyer, 25, who has bones so dense he could walk away from accidents that would leave others with broken limbs. About 100 people have sclerosteosis, Dreyer's condition.

Both men's apparent superpowers come from exceedingly uncommon deviations in their DNA.They are genetic outliers, coveted by drug companies Amgen, Genentech, and others in search of drugs for some of the industry's biggest, most lucrative markets.

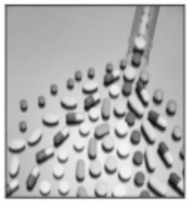
Their genes also have caused the two men enormous suffering. Pete's parents first realized something was wrong when, as a teething baby, their son almost chewed off his tongue. "That was a giant red flag," says Pete, now 34 and living in Kelso, Washington. It took doctors months to figure out he had congenital insensitivity to pain, caused by two different mutations, one inherited from each parent. On their own, the single mutations were benign; combined, they were harmful.

Dreyer, who lives in Johannes burg, was 21 months old when his parents noticed a sudden facial paralysis. Doctors first diagnosed him with palsy. Then X-rays revealed excessive bone formation in his skull, which led to a diagnosis of sclerosteosis. Nobody in Dreyer's family had the disorder; his parents both carried a single mutation, which Dreyer inherited.

Dreyer and Pete are "a gift from nature," says Andreas Grauer, global development lead for the osteoporosis drug Amgen is creating. "It is our obligation to turn it into something useful."

What's good for patients is also good for business. The painkiller market alone is worth $18 billion a year. The industry is pressing ahead with research into genetic irregularities. The US Food and Drug Administration is expected to approve a cholesterol-lowering treatment on July 24 from Sanofi and Regeneron Pharmaceuticals based on the rare gene mutation of an aerobics instructor with astoundingly low cholesterol levels.

Drugmakers are also investing in acquisitions and partnerships to get their hands on genetic information that could lead to more drugs. Amgen bought an Icelandic biotechnology company, DeCode Genetics, for $415 million in 2012, to acquire its massive database on more than half of Iceland's adult population.



Drug companies see riches in rare mutations. Drugmakers are investing in acquisitions and partnerships to get their hands on genetic information that could lead to new medicines

Source: *The Times of India, 24th July 2015*

Cancer Drug Prices in Focus

A group of 118 leading cancer experts has developed a list of proposals designed to reduce the cost of cancer drugs, and support a grassroots patient protest movement to pressure drug companies to charge what they deem a fair value for treatments. The experts include former presidents of the American Society of Clinical Oncology and the American Society of Hematology. “Its time for patients and their physicians to call for change,” said Mayo clinic haematologist DrAyalewTefferi, lead author of the paper published on Thursday in the journal Mayo Clinic Proceedings. Among the group's recommendations is the call for a new regulatory body that would help set prices once drugs win approval by the USFDA.Tefferi said such a body would be made up of disease experts, company representatives, government entities including Medicare and other major insurers, and patients. Other ideas include urging cancer specialist groups to consider cost when making treatment recommendations.

Source: *The Economic Times, 25th July 2015*

Sun Pharma Now Cuts Staff in R & D Division

Sun Pharmaceutical Industries is cutting staff again as it digests the $3.2-billion acquisition of Ranbaxy Laboratories. Facing the axe this time are Research and Development staff, a move that comes a month after about 150 senior executives were asked to leave.

Close to 15 employees from the R&D department are to exit as Sun integrates a combined staff base that's 30,000 strong. Among the erstwhile Ranbaxy executives who left in the earlier round were the head of India operations, the chief financial officer and the vice-president of marketing among others. Sun said it's trying to handle the transition as sensitively as possible.

"A thorough assessment has been made of current overlaps across the organisation," a Sun spokesperson said. "While all attempts have been made to ensure that most employees are accommodated in various positions, there will be a few who we need to help in the process of actually transitioning out of the organisation."

The acquisition, completed in March, has faced several challenges.

"We have to be realistic and prepare for adverse news ahead," managing director Dilip Shanghvi told analysts on the July 20 conference call. To achieve long term synergy , it will look at selling low-margin, non-strategic businesses such as the active pharmaceutical ingredients division. On Wednesday, Sun closed at 830 on BSE, up 1.05%.

Source: *The Economic Times, 30th July 2015*

Substance Abuse on the Rise After Bar Closure: Kerala

Home minister Ramesh Chennithala told the assembly on Wednesday that the use of narcotic products had increased three-fold in the state after the closure of bar hotels.

It has been found that various types of psychotropic drugs are being legally sold through medical stores in the state, primarily to the younger generation. At least 228 psychotropic drugs are available in the market and authorities have found that students and youths are using these drugs.

The drugs control authorities have been authorized to conduct frequent raids on medical shops across the state. “Narco terrorism is a new threat and the government is taking all steps to put an end to it. The home secretary will convene a meeting of higher officials in health and tourism departments besides drugs control authorities to chart out an action plan “Ramesh said.

He said there were reports of Maoists supporting and providing protection to ganja cultivation in the forest areas neighbouring the other states and police personnel deployed for anti-Maoist raids were monitoring the situation. It is a matter of concern that substance abuse has gone up among students and the government has launched various awareness programmes like Operation Gurukula and Our Responsibility to Children in schools to tackle this.

On films encouraging substance abuse, the minister said the home secretary would hold a discussion with censor board officials to curb such tendencies. The government has also decided to monitor the long-distance trains bringing migrant labourers to the state.

He said it had been reported that migrant labourers were being used to smuggle narcotic products into the state and police had intensified searches on trains with the support of the railway police.

Source: *The Times of India, 31st July 2015*

TN Starved of Funds to Protect Medicinal Plants

Around 14 of the 70 medicinal plants on the 'rare and endangered list' in the country are found in the Western Ghats and Tamilnadu. But the National Medicinal Plants Board has allocated only – 2.15 crore to the state for the conservation, development and sustainable management of these plants. This grant is much lower than those allocated to states like Maharashtra, Rajasthan and Madhya Pradesh.

Though it is common knowledge that a majority of the medicinal plants used in ayurveda, siddha, homeopathy and unani come from Kerala, Tamilnadu, Aruanchal Pradesh and Himachal Pradesh, 16 states have been given more funds (than Tamilnadu) to save medicinal plants this financial year.

Data submitted by the ministry of ayurveda, yoga, siddha and homeopathy (AYUSH) to the Rajya Sabha on July 21 shows that states like Maharashtra, Rajasthan and Madhya Pradesh have been allotted more than – 15 crore each.

Ancient ayurveda literature reveals that a majority of the 8,000-odd known medicinal plants in the country grow on the mountains of the Vindhyas or Western Ghats and the Himalayas, Tamilnadu where the Western Ghats begin, is thus home to many rare and endangered plant species like UrgineaIndica, Cosciniumfenestratum used to treat diabetes mellitus and intermittent fevers and AristolochiaIndica used to make snake venom, cure dry cough and purify blood.

Officials at the National Medicinal Plants Board and AYUSH said the fund crunch is because not many

proposals were received from Kerala and TN. "Under this scheme, we are likely to grant more funds to states that submit proposals on discovery and conservation of new unknown medicinal plants," said Dr. Shahidul Khair, who handles research and development funding at the ministry.

"Another factor could be that the long-term projects we funded five years ago are still incomplete," he said. According to the ministry seven years ago, Tamilnadu and Kerala were among the foremost states to receive the large funding. The ministry also justified the allocation stating that Tamilnadu stands second next only to Andhra Pradesh (Rs 29.98 crore), receiving Rs 26.90 crore in funding under the National Mission on Medicinal Plants scheme.

"This scheme helps farmers to grow and cultivate medicinal plants in the state," said another AYUSH ministry official. However, medicinal plant researchers dismiss this justification.

"We don't accept that few proposals were received from Tamilnadu and Kerala, because in the past, several proposals had been rejected, "said Dr P Ram Manohar, Director and Chief Scientific Officer at AVP Research Foundation.

"It is important to conserve them in their native places of growth. Besides, many of these plants grow only in hilly and mountainous terrain. They lose their potency when grown elsewhere," said Ram Manohar.

Source: *The Times of India, 2nd August 2015*

Home Remedies for Curing Mouth Ulcer

Mouth ulcers are one of the most painful conditions and can give you a hard time for days. The various causes of it are stress, deficiency in nutrition, food allergy and even bowel infections.

While taking B-complex tablets or using a gel can be an option, you can treat mouth ulcers with simple home remedies. They are believed to cure the ulcer faster. Here are a few tips.

Rinse your mouth with salt water at least three or four times a day. Take small quantity of salt and mix it well in warm water. Instead of rinsing swiftly, let the salt water stay in the area in which you have the ulcer for a while before you spit it out. It could hurt, but then it will gradually cure the infection. Do this after your meal. However, remember not to swallow the water.

Apply ghee or honey regularly on your ulcer. Let it stay for a while and then spit it out. Do this often and you will see your ulcer gradually shrinking.

Tulsi leaves have some wonderful properties that can make your mouth ulcer cure faster. Chew some tulsi leaves along with some warm water at least three times a day for it to cure.

Castor oil is known to relieve heat from your body. If you get mouth ulcer often, apply castor oil in the affected area. It not only cures the ulcer, but also help in easing out the heat.

Drink coconut water and butter milk every day. They will cool your body and help relieve the pain.

Avoid having spicy food, hard drinks such as tea, coffee and other aerated drinks when you have mouth ulcer. Instead, opt for fresh juices. Cranberry juice is said to help in getting rid of ulcers. Try having cranberry juice after every meal.

Source: *The Times of India, 2nd August 2015*

India Defers Trade Talks with EU Post Drugs Ban

India has decided to defer talks with the European Union on the proposed free trade agreement in protest against the ban on about 700 pharmaceutical products clinically tested by contract research organisation GVK Biosciences.

The chief negotiators of India and the EU were to meet later this month to start the stalled negotiations on the Board based Investment and Trade Agreement (BITA). The EU is India's biggest trade of nearly $ 100 billion.

"Government of India has taken a decision to defer the proposed talks between the chief negotiators on BITA for the present,"the commerce and industry ministry said in a statement on Wednesday. "This deision has been taken as the Government of India is disappointed and concerned by the action of EU in imposing legally binding ban on the sale of around 700 pharma products clinically tested by GVK Biosciences, Hyderabad".

The EU has alleged manipulation of clinical trials by GVK Biosciences. India had raised the issue with various EU regulators over the past eight months while pointing out that most of these drugs have already been there in the EU market for many years without any adverse pharmaco-vigilance report from any of the member states.

Germany's drug regulator, the Federal Institute for Medicines and Medical Products has stated that the ban, one of the largest by the EU on the sale and distribution of generic drugs, will take effect from August 21.

India is likely to face a loss of $1,2 billion because of this ban, according to Pharmaceutical Export Promotion Council of India.

"Pharmaceutical industry is one of the flagship sectors of India which has developed its reputation through strong research and safety protocols over the years and therefore, Government of India will examine all options in this regard,"the ministry said.

After a gap of about two years, India and the EU were expected to resume negotiations on the proposed free trade agreement to boost bilateral commerce and investment.

The talks, launched in June 2007, have been stuck over differences on several issues.

Source: *The Economic Times, 6th August 2015*

Ban on Indian Drugs Based on Scientific Reasons: EU

A day after India deferred trade talks with European Union (EU), protesting the ban on 700 generic drugs, the bloc said the ban was based on scientific and not trade considerations.

"The Commission stresses that the decision concerning a ban on 700 generic drugs was based on scientific and not trade considerations and in accordance with the advice of the scientific committee of the European Medicines Agency (EMA)," Daniel Rosario, European Commission Spokesperson for Trade said in an email response to The Hindu.

India said the decision was taken as the government is "disappointed and concerned by the action of EU in imposing legally binding ban on the sale of around 700 pharma products clinically tested by GVK Biosciences, Hyderabad" on 16 July, the Commerce Ministry said in a statement on Wednesday. The meeting between chief trade negotiators of the two sides was scheduled for end of this month.

"The Commission takes note of the press release issued by the Indian Government about the deferral of jointly agreed talks between the Chief

Negotiators on the EU-India Free Trade Agreement. The Commission would like to stress that the purpose of this meeting at Chief Negotiators level was to explore the possibility of resuming the FTA talks, and was not meant to constitute in anyway a full-fledged negotiation round. The Commission remains committed to continue working towards conclusion of an agreement between India and the EU that will be acceptable to both sides. For this reasons, the Commission hopes that a solution will be found to the current deferral," European Commission Spokesperson for Trade said in his email in reaction to India's action.

India and EU have been negotiating for the proposed free-trade agreements since 2007. The talks have seen set backs due to differences regarding lack of access for Indians to EU's labour market and high taxes imposed on liquor and car imports from Europe. The latest development comes as yet another setback for the talks to progress further.

The country could lose about $1-1.2 billion worth of drug exports because of the decision taken by the European Commission to ban the drugs, according to Pharmaceuticals Export Promotion Council (Pharmexcil).

India exported $15.4 billion worth of pharmaceutical products in 2014-15, with Europe accounting for $3 billion, or 20 per cent of the total. Out of the $3 billion, exports of generic medicines constituted about $1 billion and drug ingredients accounted for the rest.

Source: *The Hindu, 7th August 2015*

Dr Reddy's Seeks Licensing Pacts to Spur Local Sales

Dr Reddy's Laboratories (DRL), the nation's second largest drug maker by revenue, is in talks with some European and Japanese giants to form licensing or marketing agreements to sell their medicines in the Rs 90,000 crore domestic market, a strategy aimed primarily at swiftly improving local market share and profit.

The Hyderabad-based company, which has been witnessing impressive growth in domestic sales of late, views that it had missed a significant growth opportunity earlier owing to inadequate focus on the home market.

Chief Financial Officer Saumen Chakraborty confirmed the ongoing talks with global firms for in-licensing agreements, but refused to divulge details. Alok Sonig, executive vice president and head of India and global business development, said the talks were "part of ongoing business development work". "In-licensing agreements help companies quickly improve product basket and market share at an average royalty payments of around 15%,"said a Mumbai-based analyst at a foreign brokerage.

While Dr Reddy's has improved its position to 14th in terms of local sales from 16th one year earlier, the company still realises that it missed the Indian growth story, the analyst said, speaking on the condition of anonymity.

"It is now looking at strengthening its position in the domestic market and forging several value-accretive in-licensing agreements to sell expensive and high-margin medicines in certain key therapeutic segments and cardiology in India. The Indian company will offer Amgen regulatory and commercial services to launch the products.

The company is seeking to in-license products across the core therapy areas of gastro-intestinal, cardiovascular, diabetes, oncology, nephrology, respiratory, pain, dermatology, neurology and urology, Sonig told ET. "This is in line with our corporate objectives to accelerate access to innovative medicines. Many of our prospective partners do not have presence in India and their patented innovative products require a solid local

commercial partner to make the drugs accessible for Indian patients," he said.

On Thursday, Dr Reddy's announced a strategic partnership with US-based biotechnology firm Amgen to market and distribute three of its medicines in the areas of oncology and cardiology in India.

The Indian company will offer Amgen regulatory and commercial services to launch the products.

“Drug firms normally look at in-licensing products in the areas of chronic therapeutic segments that enable both high volumes and margins, “the analyst said.

“As against an average growth of 10% in acute segment, the growth chronic therapeutic segment has been hovering at a high of 20% over the last four-five years in India.” Dr Reddy's currently has multiple agreements with global giants including Biocodex of France. Astra-Zeneca of the UK, Ferrer of Spain, Salix of the US and Switzerland's Debiopharm, said Sonig.

“We aspire to grow much faster than the overall market,” he said, adding that the company would “continue to look at companies that would be strategic fit for our business and where we will be able to add value through our commercial excellence efforts.”

Dr Reddy's launched six products in the domestic market and acquired Belgium company UCB's Indian assets for around Rs 800 crore in the past fiscal year.

Source: *The Economic Times, 7th August 2015*

Net Meds Goes Pan-India

The online pharmacy space, which attracted the attention of authorities in the recent past for the wrong reasons, is set to take off in a big way in India with the proliferation of mobile phones and apps.

Even as the Drug Controller General of India (DCGI) is setting up a framework for online pharmacies to operate in the country, NetMeds.com, which has the requisite licenses in place, has launched the first pan-India solution in the market.

NetMeds last week launched its mobile app, which can be downloaded on Android or iPhones and has tied up with the government's India Post to provide delivery services nation-wide.

The app offers the entire catalogue of more than 50,000 drugs available to those with a valid prescription and a smartphone.

While India's Rs.85,000-crore pharmaceutical industry is growing in double digits, PradeepDadha, CEO, NetMeds, told this correspondent that the online pharmacy industry could grow to 4-5 per cent of total industry reaching Rs.5,000 crore in the next five years.

“Some marketplaces were operating in violation of the provisions of the Drugs & Cosmetics Act and not dispensing the drugs from a licensed premise which is why the issues cropped up recently,” Mr. Dadha said.

This is why the DCGI is now formulating guidelines as the existing Drugs & Cosmetics Act has no guidelines in place for e-pharmacies. The DCGI had then observed that the interest of small retailers would be protected and existing supply chains would not be adversely impacted by e-pharmacies. The aim was to integrate e-pharmacy into the existing system, he said.

On fears expressed by brick and mortar pharmacies and the opposition from bodies such as All India Organization of Chemists and Druggists (AIOCD) on e-pharmacy, Mr. Dadha said “there was an initial negative reaction from them but online pharmacies will only support and supplement existing pharmacies and are a step towards 'Access for All' ensuring patients get medicines even in far-flung areas.”

"Our primary target is to cater to chronic conditions such as diabetes, hypertension and cholesterol control and provide month-on-month medicines. We do not cater to emergencies or acute care. Even internationally, mail order pharmacies follow a similar model," he said.

NetMeds' competitors include mChemist and 1mg although these are more metro-centric. On prospective competition, Mr. Dadha said, "Dadha Pharmaceuticals have been in the business for 100 years and one needs domain expertise."

NetMeds launched 'Health Memo' an app to electronically store patient records on the cloud including X-rays, MRI scans etc. and it will be soon integrated into its app. It uses its in-house depot in Kerala for warehousing.

NetMeds raised Rs.60 crore from promoters and Mape Advisory. In the medium-term, it expects funding requirement of Rs.200 crore, "depending on the traction the business generates. It would be used towards marketing, creation of depots and wholesaler tie-ups."

Source: *The Hindu, 10th August 2015*

Domestic Pharma Retail Mkt Tops Rs90k Cr

Domestic organized pharma retail market crossed Rs 90,000 crore for the first time ever in cumulative sales, driven by a huge growth in sales of anti-diabetic drugs, dermatology and urology medicines. In July, the pharma retail market recorded a robust growth of nearly 13% of Rs 8,328 crore, adding Rs 1,019 crore over July 2014 — the highest incremental value for the month in the last three years.

Significantly, the growth is also the fastest witnessed in recent years — the market took over two years to move from the Rs 66,000 crore to the Rs 80,000 croremark, while it crossed Rs 90,000 crore in lesser time. The market added Rs 11,258 crore in just a year (MAT June 2015 over MAT June 2014), as against Rs 11,851 crore recorded over a two-year period (MAT June 2014 over MAT June 2012), data culled from pharma research firm AIOCD AWACS said.

With the good performance in July, the pharma retail market has witnessed a continuous nine months of double-digit growth. During the month, among the top 10 companies, Lupin grew by 25% followed by Sun Pharma at 22% and Pfizer at 17% — domestic companies have grown at 12.6%, as against a higher growth of 13.8% for MNCs. Over the 12-month period, new players including Koye, Saffron Therapeutics, Arianna, Kepler Healthcare have emerged.

Among the top-selling medicines in July, Mixtard leads the pack with sales of Rs 42 crore, followed by Spasmoproxyvon Plus at Rs 30 crore and Glycomet-GP at Rs 28 crore. Cold and cough preparation Phensedyl Cough grew by 133%, followed by cough syrup Corex at 103%, diabetic drug Janumet at 93.4%, insulin drug Mixtard at 37.4%. The robust growth in July was attributed to nine therapies having outgrown the pharma market, with the anti-diabetic market growing at 25.4%, cardiac drugs at 17.1%, derma market at 19.4% and urology drugs at 18.6%.

Source: *The Times of India, 11th August 2015*

Pharma MNCs up India Play WithBlockbuster Show

Far from drawing a gloomy picture of India, global drug makers seem to have turned gung ho on the country.

Most of them are introducing new patented medicines. While some of the biggest multinational firms like Johnson & Johnson, Novartis, BoehringerIngelheim, Gilead andAstraZeneca launched their most promising brands across therapy areas in India, others such as Bristol-Myers Squibb (BMS) and Amgen are setting themselves up for a bigger role in the Rs 90,000 crore India market that is growing in mid-teens, outshining other emerging markets.

In fact, pharma MNCs in India are growing faster than their local counterparts: according to AIOCD data, they expanded 13.8 per cent in July, compared with 12.6 per cent by Indian companies.

The newfound optimism runs counter to the wide scepticism revolving around the much debated intellectual property laws and a looming uncertainty over clinical trial regulations and drug pricing policies in India. VK Subburaj, secretary to the Department of Pharmaceuticals, last week told reporters that a committee was still deliberating on a framework for pricing of patented drugs.

A change in prioritising a commercial revamp is in the air. Swiss drug maker Novartis that witnessed drawn-out patent related litigations in India — first oncancer drug Gleevec and more recently on respiratory treatment Onbrez has launched Sequadra, an advanced treatment for patients with chronic respiratory issues. "India is both a challenging and an exciting market," said Jawed Zia, country president at Novartis India. "Novartis has a rich pipeline in respiratory, dermatology, cardiovascular and retina. India participates in the extensive clinical trials associated with this pipeline ... Novartis is committed to bringing the latest therapies to India soon after their global launch to the long term benefit of the patient," he said.

Source: *The Economic Times, 14th August 2015*

India Rejects Lee Pharma's Compulsory Licence Plea

India has decided against giving the compulsory licence for Anglo-Swedish drugmaker AstraZeneca's key antidiabetes compound Saxagliptin sought by Hyderabad-based Lee Pharma. The Controller of Patents office rejected the application on the grounds that substitutes to the drug are readily available in the market and Lee Pharma's claim that requirements of public with respect to the patented invention are not being satisfied has not been proven.

Saxagliptin, sold under the brand. Onglyza and Kombiglyze, is prescribed for type-II diabetes mellitus, which occurs when the pancreas does not produce enough insulin or when body does not effectively utilise the insulin produced.

The patent for manufacturing and selling Saxagliptin compound was granted to Bristol Myers Squibb on April 30, 2007 and then transferred to London-headquartered AstraZeneca. The renewal fee for the patent has been paid till March 5, 2016.

Section 84(1) of Patents Act 1970 states that after the expiration of three years from the date of grant of patent any person may make an application for grant of compulsory licence on three grounds - the reasonable requirements of the public have not been satisfied or the patented invention is not available to the public at an affordable price or the patented invention is not worked in the territory of India.

The Controller of Patents office turned down Lee Pharma's application on all the three grounds. Rajiv Aggarwal, controller of patents, said that manufacture in India is not a necessary precondition in all cases to establish working in India.

"The applicant has failed to prima facie show that the patented invention is not worked in the territory of India...I am therefore of the view that case has not been made out for the making of an order under Section 84," Aggarwal said in his order, a copy of which was seen by ET.

Although Lee Pharma had contended that AstraZenecaBSE 0.39 % had fixed a high price for tablets of the two medicines, Onglyza and Kombiglyze, the controller of patents found Lee Pharma's proposed selling pricce several times the import cost and only marginally below that of AstraZeneca. This also prompted the controller to turn down the application.

Source: *The Economic Times, 18thAugust 2015*

German Pharma Shuts Down B'luru R & D Unit

German pharmaceutical and life sciences company Merck KGaA has decided to close down Bangalore GeNei, a company it had acquired in 2009 to bolster capabilities in design, development and production of biological research products, according to people aware of the development.

A spokesperson for Merck India confirmed it saying the decision was taken at the beginning of the year and production at the site was stopped on July 31. "Decommissioning activities are going on," the spokesperson said.

The Indian arm of $12.5-billion Merck KGaA said selling the facility has been considered as an option during the decision process and opportunities are being evaluated. As part of the strategy for Merck Millipore, its global arm that deals with reagents, chemicals and labware, the company said it has been decided to stop supply of GeNei products and close the Merck Bangalore Site 02 - GeNei facility.

"Merck Millipore will systematically stop the sale of teaching kits, tech ware and molecular biology reagents and custom service of GeNei," the spokesperson said. Bangalore GeNei employed 39 full-time employees and 12 contract personnel. Merck said its management has been in detailed dialogue with the impacted employees, supporting their transition and evaluating alternate opportunities where possible.

Merck Millipore is expected to continue to focus on its core businesses like genomics, proteomics, cell culture, cell analysis, western blotting, disease research tools, analytical sample preparation and bio chemicals.

In an interview with ET earlier this month, Merck's global CEO Belen Garijo had said India is one of its key growth markets under a global expansion drive.

Source: *The Economic Times, 24th August 2015*

Glenmark Expects USFDA Nod for 4-6 Products This Yr

Glenmark Pharmaceuticals is expecting approvals for four to six new products during the fiscal from the US Food and Drug Administration (USFDA), a senior official said on Monday.

"We are expecting approvals for 4-6 products from the USFDA during this year," Glenmark Pharmaceuticals President and Head-India Business Sujesh Vasudevan told reporters here on the sidelines of launch of Teneligliptin in Telangana.

The company had already got approvals for eight products this year, he added. Teneligliptin, a new third generation oral anti-diabetic agent, is used for the management of Type 2 Diabetes Mellitus. Glenmark has launched this molecule under two brands, Ziten and Zita Plus, at Rs 19.90 per tablet.

“The launch of these two products will lower the daily cost of treatment for a diabetes patient on Gliptin therapy by approximately 55 percent," Vasudevan said. Glenmark's diabetes segment is valued at around Rs 100 crore, Vasudevan said, adding it is growing at 20 percent per annum.

Source: *The Economic Times, 25th August 2015*

Centre Plans A VC Fund For Pharma Sect

The Department of Pharmaceuticals, government of India is in the process to create a venture capital fund with a 1,000 crore corpus which will invest in pharma start-ups.

"This is still in the formulation stage and the whole idea is to usher in the start-up culture in the pharma space wherein young minds can develop molecules in incubation centres which can then be bought over by big pharma players and that drug discovery is no longer the prerogative of larger players alone," M Ariz Ahammed, Joint Secretary, Department of Pharmaceuticals, Government of India said.

Ahammed added that such a venture capital funding would help meet the nation's disease burden needs.

"We need to become leaders in drug discovery and for that we need to do good investment in human resources and talent."

The turnover of the Indian pharmaceutical market is 2 lakh crore; in which the domestic pie is 95,000 crore.

The Joint Secretary said that while 99% of drugs in the domestic market continue to be generic medicines, in the western world more than 70% are patent drugs.

"Our disease pattern is shifting from communicable to non-communicable diseases like cancer, neurological and mental disorders.

So its imperative to enter the drug discovery race otherwise affordability and access to medicines will remain elusive" he said.

"In India, 70% of health care costs are borne by individuals, estimates suggest 2% of India's population is becoming poorer every year due to rising healthcare costs," the joint secretary said.

Ahammed also said that the DPR (detailed project report) for establishing a NIPER (National Institute of Pharmaceutical Education and Research) at Madurai was over.

“The cabinet approval for NIPER, Madurai will come in the next six months after which construction would commence,”Ahammed said.

The investment for the NIPER centre in Madurai is expected to be Rs 500 crore.

Source: *The Times of India, 27th August 2015*

Corner Offices Vacant in Pharma Industry

The consolidation and steady growth witnessed in the over Rs 90,000-crore domestic pharma market have led to openings in top leadership roles with at least three drug companies on the lookout for CEOs. Pfizer, Baxter and Meiji Pharma are all looking to fill the top slots at their domestic operations, industry sources said. This is even as Hyderabad-based Aurobindo has appointed Sanjeev Dani, the former Ranbaxy executive VP, as COO.

Meiji Holdings of Japan, which closed the $290-million acquisition of domestic company Medreich this year, is scouting for a person to head its operations here. The transaction will help the Japanese company to expand its play in the global generic drugs sector, since the Bangalore-based mid-sized contract development and manufacturing firm has tie-ups with global drug majors. Medreich, with six manufacturing facilities in India and a unit in Europe, reportedly clocked revenues of $175 million in FY14, with 80 per cent coming from exports.

iStock/Getty Images

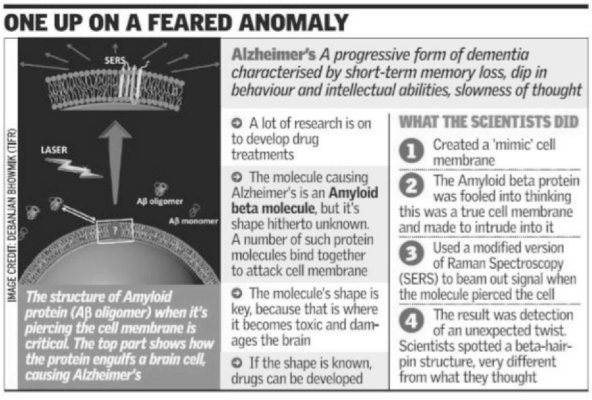
A global restructuring at healthcare firm Baxter will also lead to a vacant slot of a person to head the operations in India, an industry expert said, adding the existing country head, AnishBafna, is moving to a regional role. An email sent to the company remained unanswered. Under the restructuring, Baxter is divesting its biotechnology operations into a publicly traded company to focus on its core medical technology business. Baxter's global revenues are over $16 billion.

Mayank Chandra, managing partner, Antal International, a global executive recruitment firm, said, "Mergers and acquisitions are happening in the pharma and healthcare (CRO, medical devices, etc) sector, leading to big shifts. The domestic pharma market is pegged at Rs 90,000 crore and existing players are in an expansion mode as regards their product portfolio, and are also inclined to add new molecules. Hence, they look for people with an upgraded technical background and successful track records. Right now, companies are actively seeking pharma leaders who have experience abroad and are willing to relocate to India. This includes not just PIOs (persons of Indian origin) but also expats. Definitely, the consolidation has helped make a big shift in leadership roles across disciplines."

Drug MNC Pfizer India, too, is still on the lookout for a country manager to head the operations here. Many in industry circles are surprised that the position has not been filled in the last couple of months. The company, which clocked a turnover of over Rs 1,800 crore, had announced in June that it will appoint a new India head, with current MD Aijaz Tobaccowalla being offered a global role with the parent.

Source: *The Times of India, 27th August 2015*

Researchers One Step Closer to Cracking Alzheimer's Puzzle



Research groups at TIFR, Mumbai, IISc, Bangalore and the University of Toronto working together, may have gotten the closest yet to figuring out how the toxic form of the Alzheimer's molecule looks. This brings with it implications of development of better drugs to treat patients.

Alzheimer's disease is a progressive form of dementia that is characterised by loss of short-term memory, deterioration in behaviour and intellectual performance, besides slowness of thought. It may occur in middle age or in old age, and while a lot of research is on for drug treatments, none has been successful.

While it is widely accepted that a specific form of the Amyloid beta molecule is a major player in causing Alzheimer's, the shape and form of this remained elusive, experts say. The excitement now is that scientists have caught a glimpse of the molecule during its attempt to enter a cell membrane, using a new method involving laser light and fat-coated silver nanoparticles.

“It is a rare protein and is difficult to probe. It was slightly fortuitous that we found it, using a modified version of Raman Spectroscopy. Usually the signal from this is weak, but we mimicked the cell's outer layer by encasing silver nanoparticles in a fat membrane,” says SudiptaMaiti, of TIFR, who co-directed the research with P.K. Madhu. The Amyloid beta molecules were fooled into piercing this 'membrane' and the nanoparticles enhanced the signals, allowing scientists to see it at that point.

When proteins aggregate, or gang up to form a structure, they shift shapes. “At some stage of ganging up they suddenly start attacking the cell membrane and that's where toxicity begins. How they enter the membrane, and what they look like when entering the membrane is key,” he says.

Amyloid beta molecules

The 'lock' looks like a bunch of Amyloid beta molecules each in the shape of a hairpin, but with a twist, TIFR has said in a release.

DebanjanBhowmik, the lead contributor of the study, says “This has been suspected earlier, but what we found was an unexpected twist in the structure, now becoming a beta-hairpin — very different from the typical hairpin structure people imagined.” This technique might also help in finding the shape of similar proteins in future, Dr. Maiti adds.

The findings were published in the journal ACS Nano this week.

If indeed it turns out to be the 'lock' for Alzheimer's then the discovery will facilitate new efforts to finding a key — an intelligent drug candidate designed to attack the lock. “We have been working on the project for nearly 12 years now, and it is only now that we have started working with a few colleagues from the Institute of Chemical Technology who have the expertise in the field of intelligent design of drug molecules,” Dr. Maiti says.

“The use of technology to identify peptides and peptide transformations, which helps us understand the structure in great detail, is important — both for definitive diagnosis and definitive treatments. Once defined, researchers could adopt the technique to study wider samples, and this will lead to a greater understanding and modification of processes, eventually to better clinical care,” says Ennapadam S. Krishnamoorthy, Chennai-based senior neuropsychiatrist, and founder, Neurokrish.

Source: *The Hindu, 29th August 2015*

Antibiotic Overuse May Increase Diabetes Risk

Taking too many antibiotics could increase your risk of developing type 2 diabetes, a new study has warned. People who developed Type 2 diabetes tended to take more antibiotics in the years leading up to the diagnosis than people who did not have the condition, researchers found. “In our research, we found people who have Type 2 diabetes used significantly more antibiotics up to 15 years prior to diagnosis compared to healthy controls,”said one of the study's authors. Kristian Hallundbak Mikkelsen, of Gentofte Hospital in Denmark.

Source: *The Times of India, 29th August 2015*

Summer-Friendly Goodness

Among the treats that summer has in store for us, we have the jamun, or naval pazham, if you prefer. Its botanical name is SyzygiumCumini, with the centre of origin being India, from where it has spread to various tropical countries, sometimes courtesy the Indian indentured immigrants, and sometimes through colonisers such as the Portuguese. This can only be a measure of its worth.

The black plum, as the deep-purple ripe fruit is called, is eminently summer-friendly, given its nutritional profile: 100 g of jamun contains 84.75 g of water. Combined with minerals comprising 35 mg of magnesium, 15mg of phosphorus, 26.2 mg of sodium, it makes jamun laced with rock salt a perfect snack for a sweltering hot day, all the more so, given the sweet, sour and astringent tastes of the berry.

As per Ayurveda, jamun — fruit, leaves, bark and seeds included — has many therapeutic properties. The fruit is a coolant, increases vatta, balances pitta and improves digestion; the leaves too contribute to digestive as well as oral health; triggering constipation, they are effective in the treatment of diarrhoea. As for the seeds, they are star performers in the control of diabetes, converting sugar into energy.

Coming back to the nutritional content of the fruit and various parts of the plant, we see that the leaves, the bark and the seeds are a good source of malic and oxalic acids, in addition to tannins, which are anti-malarial, anti-bacterial and gastro-protective. The fruit packs in 15 mg of calcium, 1.41 mg of iron, 18 mg of vitamin C, a certain amount of vitamins B1, B2, B3 and B6, all of which are beneficial for bodily functions and building immunity. Besides these, the polyphenol compounds of jamun are effective against cancer, heart diseases, asthma and arthritis.

The vinegar made from the fruit is equally full of benefits; it is high in vitamins A and C, two important elements promoting immunity, bone health and good vision. In traditional medicine, the vinegar is prescribed for digestive problems as well as spleen and liver health. Moreover, it is considered to be a blood thinner, and therefore, good for circulation, while its iron content ensures oxygen supply to the blood, thereby purifying it. Being diuretic, it helps people suffering from water retention ailments.

From the cosmetic angle too, the vinegar is deemed effective for both hair and skin, especially oily skin, given its astringent property, which does wonders to control acne, the bane of many a teenager.

This fruit, laden as it is with goodness, is unfortunately available only for a brief period during summer; one can enjoy them, as such, or in a raita to which rock salt has been added, or even, as some innovative chefs have done, in the form of ice-cream.

The good news, however, is that, to stretch its usage beyond its season, human ingenuity has

found various solutions. Of course, there is the vinegar, which means a wine too can be made. Jamun juice and syrup are also available. The pulp of the fruit can be canned or processed into jams and sauces.

Let us ensure the availability of this amazing endemic tree to future generations by planting someJambu trees in the monsoon and truly earn our mythical pseudonym Jambudvipa, the Land of theJambu tree, a symbol of the terrestrial world as per Hindu, Buddhist and Jain cosmologies.

Source: *The Hindu, 29th August 2015*

Pharma Companies 'Push' Costly Insulin at Expense of Patients

This may come as a shocker. Newer and more expensive categories of insulin are being aggressively "pushed" by drug companies, and, hence, increasingly prescribed by physicians for diabetics. The newer, second generation (rapid and long acting) versions are priced around Rs 500, three to four times costlier than the older versions - increasing the cost of treatment. Diabetes is growing alarmingly in India, with over 65 million patients now. About 30-35 per cent of these are on insulin, while 70 80 per cent of them prescribed insulin therapy in their lifetime.

These aggressive promotions are rampant globally too, with the surge in cost of diabetes therapy sparking off a debate in the medical fraternity, and among patients.

The matter assumes significance as it was discussed at the annual American Diabetic Association held in Boston recently. For years, drugmakers' reputations have been tarnished due to unethical and aggressive prescription promotion to doctors,says Anoop Misra, Chairman of Fortis Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology. “I strongly believe some newer and costly insulin are being `pushed' to physicians and patients in India, while it has been inferred from debates even in the US that there is no advantage of newer insulin that are nearly 4-6 times costlier than older insulin.“

The older insulin, while less commonly used, are as effective as the analogs (new versions) at controlling blood glucose for most type 2 diabetes patients, but at a lower price.

As far as clinical outcomes are concerned, despite the increased use of the newer versions, their superiority compared with human insulin is not well established, particularly for type 2 diabetes. The original regular insulin has a duration of action of about 8 hours, making it poorly suited to provide 24 hour basal coverage.

Source: *The Times of India, 30th August 2015*

When US, UK Docs Refuse to Prescribe Made-In-India Drugs, it Reeks of Racism

Greg Jefferys, a 61-year-old historian and author from Australia, hit international headlines when he flew to Chennai to use generic Sofosbuvir to successfully cure himself of Hepatitis C. He spent 1/100th — just about $1000 — the amount it would have cost him if he were to use the patented version. Jefferys has since helped hundreds of patients access the medicine cheaply from here. Talking to Rema Nagarajan, Jefferys strongly criticises big pharma and the patent regime that is putting life-saving medicines beyond the reach of patients and allowing companies to make 'obscene profits'

Did you have concerns regarding the safety and quality of the Indian Sofosbuvir?

I have no concerns about Indian generics generally. In all areas of the world, there are issues of quality control and there are good companies and not-so-good companies. India has some of the largest and best pharmaceutical manufacturers in the world. I actually get really angry when doctors in the UK or the US refuse to prescribe life-saving drugs because they are made in India. It reeks of racism or post-colonial arrogance! Did you know that I have had dozens of emails from people in the UK with hep C who have tried to get a prescription for Indian Sofosbuvir and not one doctor in all of the UK would write it for these people. But I have had two prescriptions for Indian Sofosbuvir from the UK. One was from a doctor who had hep C himself and the other was from a doctor whose best friend had hep C. None other than that! It astounds me. Tens of thousands of people in the UK are suffering and dying simply because their GPs refuse to write them a prescription for Indian generic medicines!

In Australia it is not illegal to bring in three months' supply of a drug. But what about countries where it is illegal to bring in drugs from other countries? What should they do?

Most countries have laws favourable to their citizens importing medicines for personal use. There are only seven that I know of that totally prohibit this and I would suggest that if I lived in one of those countries then I would bring the medicines in to save my life or the life of a loved one. Who would not!

Do you think there is a need for a worldwide civil disobedience movement to force governments to re-examine pricing of life-saving medicines?

I think that people should embrace the affordable and life-saving medicines being offered to the world by India, import them and use them. Their governments and advocates should encourage this but they do not because they are scared of the power and wealth of big pharma. Big pharma has developed many strategies to prevent this. At the moment there is an extensive campaign in Australia, the UK and the US to instil fear of Indian generics in both doctors and the general public. This is done by whispers, cleverly placed press releases and out and out bribery. For example, the main hepatitis advocacy group in Australia, Hepatitis Australia, receives $240,000 per annum in "sponsorship" from drug companies. Hep Australia generally discourages people from using Indian generics. This is the case with most hep advocacy groups around the world. They all get major financial sponsorship from the drug companies. They claim this does not influence them but we all know that it does.

Also, doctors, hospitals and medical universities all get major funding from the drug companies for research projects. It is supposed to be "at arms length" but is it?

What do you say about high pricing blocking access to a medicine that could possibly eradicate hep C virus of a particular kind?

The medicines that are now available could eliminate hep C from the earth in a decade but the greed of big companies prevents this. I am happy for drug companies to make a profit, a healthy profit, not an obscene profit, not a profit that means that tens of millions of people will suffer and die simply because they do not have enough money to pay the outrageous prices being asked for these medicines.

Does it make sense to grant patents and protect predatory pricing even when pharma companies are not ready to open up their account books or make public how much it cost to 'discover' a drug? What do you think should be done? Is there a need to revisit or change the patent regime currently being enforced internationally?

I believe India has the correct attitude to patents, particularly drug patents. Set the bar high. Something must be truly innovative, not just an existing concept that has been slightly reworked, which is the case with Sovaldi and the other new antivirals. Set the bar high, if it is not innovative enough then let the product be manufactured and sold on the open market. Big pharma uses its vast wealth to influence politicians and governments around the world to try to get them to set the patent bar low. I applaud India for standing strong and independent against the pressure of western commercial forces. It is incredibly important that there are countries like India that are independent and able to stand up against the pressures from places like the US. India is a beacon of hope for the world and for so many people, like myself, who would die if it was not for India making these generic drugs available.

Why did you decide on Chennai? What was your experience like?

I have been to India a number of times but never to the south. I recently wrote a history book which was largely about an officer in the East India Company who was based in Madras from 1790 to 1812 so I wanted to see Chennai. It was very hot... 40+ nearly every day. But I enjoyed it. I always enjoy India.

Source: *The Times of India, 30th August 2015*

Cipla to Buy 2 US Cos for $550 M

Drug major Cipla has entered into agreements to acquire US-based InvaGen Pharmaceuticals and Exelan Pharmaceuticals, owned by one of the promoters of Hetero Group, in an allcash transaction of $550 million (approxRs 3,652 crore).

The deals, through its UK arm Cipla EU, are subject to certain closing conditions, Cipla said in a statement.

This acquisition will give Cipla scale in the US generics market through a wide ranging product portfolio in CNS, CVS, anti-infectives, diabetes as well as other value-added generics, the company said.

Cipla MD and Global chief executive SubhanuSaxena said: “This investment is in line with Cipla's strategy to grow its share in the US pharmaceutical market.“

The company sees InvaGen as a strong strategic fit with a relevant diverse portfolio as well as a strong market and customer presence, he said.

With a local manufacturing facility, it can urther strengthen its presence and commitment to serve patients in the country , he added.

InvaGen offers a large capacity manufacturing base in Hauppauge, NY and a skilled US-based R&D organization. The acquisition of InvaGen pharmaceuticals also provides Cipla with about 40 approved ANDAs, 32 marketed products, and 30 pipeline products which are expected to be approved over the next 4 years, Cipla said.

The acquisition of Exelan provides Cipla access to government and institutional market in the US, Cipla said.

“We are confident that the combination of InvaGen and Cipla will significantly enhance the product portfolio offering, including specialty products, to the US patients and will give InvaGen access to Cipla's global expertise and presence,“InvaGen president and CEO Sudhakar Vidiyala said.

Source: *The Times of India, 5th September 2015*

Is Roundup Herbicide Really Safe?

Even short-term use of the world's most popular herbicide, Roundup, could lead to a range of health problems including steroidal hormonal imbalances, says a new study.

Published in the journal Toxicology Reports, Medhamurthy Rudraiah and Aparamita Pandey — both from Department of Molecular Reproduction, Development and Genetics, Indian Institute of Science (IISc), Bengaluru — have found that Roundup, the best-selling herbicide, produced and manufactured by Monsanto, can cause imbalances in the synthesis of steroid hormones in male rats.

Previous studies have linked the herbicide — which contains glyphosate — to diseases such as Parkinson's, infertility and skin cancer. The herbicide kills weeds by inhibiting enzymes that synthesise aromatic amino acids essential for plant development. As humans and mammals do not have the enzymes, the herbicide was marketed as being a non-toxic alternative to chemicals.

The IISc researchers subjected male rats to varying levels of Roundup exposure — the minimum being just 10 mg per kg of the rat while the maximum dosage was 250 mg per kg. The rats were orally administered the weed killer for two weeks.

The outcome of the experiment is cause for concern: male rats were seen with decreasing testosterone production (which affects sexual functions) as well as Adreno-Cortico-Tropic Hormone from the pituitary gland (which affects the body's ability in maintaining normal glucose and fat metabolism).

Both testosterone and corticosterone were down by more than 33 per cent even at the lowest doses of 10 mg and 50 mg daily. The RNA expression of receptors for cholesterol uptake (low density lipoprotein receptor) was found to be significantly lower, notes the study. In effect, the rats seem to eat less as the course continued. Those exposed to 250 mg per day ate less than half the food as was eaten by the control group, while their body weight decreased by 33 per cent in just two weeks. Even rats administered just 10 mg of the herbicide daily saw a marginal six per cent reduction in weight. “It is therefore highly possible that the herbicide affects other endocrine glands as well…and these results were seen in just two weeks of exposure. The herbicide must be investigated as the weed killer is used extensively”, says Ms. Aparamita, first author of the study.

Source: *The Hindu, 7th September 2015*

India Rejects Pfizer's Patent on Arthritis Drug

India has again denied Pfizer Inc a patent on its rheumatoid arthritis drug tofacitinib, the latest setback for a multinational drugmaker seeking to enforce its intellectual property rights in the country.

Pfizer sought a patent that covers an important chemical formulation of the active compound in the medicine, but the Indian Patent Office said the company would have to establish that the compound for which it is seeking a patent is therapeutically more effective than the active compound.

"The invention disclosed and claimed in the instant application is not considered as an invention under the provisions of the Act," Bharat N S, an assistant controller at the patent office, wrote in an order dated Sept. 3.

Pfizer is reviewing its options for further action, a Mumbai-based company spokesman said in an emailed statement.

Drug patents have become a thorny issue for global drugmakers seeking to expand in India's fast-growing healthcare market.

Companies including Pfizer, Bayer and Roche have in recent years struggled to retain exclusivity on drugs in India, and have blamed patent laws they say are designed to favor the local industry.

India, however, has said its drug patents policy is designed to ensure medicines remain affordable for the country where less than 15 percent of the population has health insurance.

India's patent office had rejected Pfizer's application to patent tofacitinib in 2011, but was ordered to reconsider the decision by the Intellectual Property Appellate Board, after Pfizer appealed.

Source: *The Times of India, 8th September 2015*

PICS Norms to Boost Drug Co's Vitality

Good news for drug exporters upgrading manufacturing facilities to meet Geneva-based standards to give local Pharma co access to 45 export markets. However, SME players focusing only on domestic markets see it as a financial burden

India is looking at persuading thousands of drug makers to upgrade their manufacturing facilities to help the country meet PICS standards, which will allow local companies access 45 export markets.

Geneva-based PICS (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme) has been insisting that India join the league so that exporters can avoid multiple regulatory checks on drugs and manufacturing facilities. The member countries of PICS procure drugs from the facilities of fellow member countries without duplicating inspections on the drugs and facilities, helping exporters substantially save on time and money.

India's commerce ministry, which had earlier advised its drug makers to consider joining PICS, is now planning to host comprehensive meetings with trade bodies along with a technical session this month to decide on a timeframe for compliance.

The prescribed standards of the PICS alliance, comprising the US and European countries, include Good Clinical Practice (GCP) and Good Pharmaco-vigilance Practice (GPP), apart from Good Manufacturing Practice (GMP).

"The commerce ministry is planning to hold an open forum of pharma producers in Hyderabad during the fourth week of this month for an initial round of awareness creation on the advantages of joining the PICS league," a senior commerce ministry bureaucrat told ET, requesting anonymity. "We will take it forward with another round of detailed talks with the trade bodies sometime during next month or so."

He, however, admitted that many small and medium pharma firms, especially those focussing solely on the domestic market, were averse to India joining the league given the costs involved in upgrading their facilities.

“It costs at least Rs 5 crore per unit to upgrade manufacturing standards to comply with PICS specifications, proving it an unwarranted burden on SMEs focussing only on the domestic market," said a senior executive of a mid-size drug maker based out of Hyderabad. "Joining PICS league will of course be of significant benefit to the exporters."

Confirming the preparations of the commerce ministry on PICS compliance, Pharmaceuticals Export Promotion Council Director-General PV Appaji said the government is aware of the apprehensions of SME drug makers. It will go ahead with PICS compliance only after convincing all the stakeholders, he told ET. "The proposed awareness conclaves and talks with trade bodies were aimed at this purpose."

India, the third largest global pharma producer, has nearly 10,000 drug units with less than a sixth of them, mostly exporters, certified with WHO-GMP standards. The government's decision to join the PICS league will make more than 8,600 units to invest sizeable amounts on upgrading their facilities. India currently exports over Rs 94,000 crore worth of medicines and more than two-thirds of the products go to PICS member countries.

“The SMEs want the government to look at extending incentives and soft loans to upgrade their facilities to meet the PICS standards, which helps them access 45 member markets nad improve their revenues and profits to recover investments,” said a senior drug administrator in Telangana.

The proposal to join the PICS league will lead to financial burden on the government as well, said M AmruthaRao, deputy director and drug licensing authority at Telangana's Drug Control Administration.

“We need to augment the strength of drug inspectors and other regulatory staff to ensure that all the drug makers including the SMEs adhere to the new PICS standards.

The government has agreed to spend over Rs

8,000 crore to strengthen the regulatory mechanism and setting up new drug testing laboratories over the next five years, which will come in handy for the PICS compliance as well".

Upgrading Standards

WHAT'S THE ADVANTAGE

Compliance to PICS will avoid multiple regulatory checks on drug and manufacturing facilities for exporters

Member countries of PICS can procure drugs from of fellow member countries without duplicating inspections on the drugs and facilities

94,000 cr Indian drug exports

10,000 Drug making units across country

8,600 Units that will have to upgrade to PICS league by govt's decision

Source: *The Economic Times, 10th September 2015*

Can Indian Generic Makers Find Gold With A Blockbuster Hepatitis C Drug?

For patients with Hepatitis C, Dr. Parveen Malhotra prescribes a tablet that doctors say is revolutionising the treatment paradigm for the dreaded liver ailment. The hepatologist from Haryana's Rohtak town too has reported a higher cure rate since switching to the orally administered sofosbuvir from the injectable interferon five months ago.

According to World Health Organization data, hepatitis C kills half a million people a year and infects 150 million globally. Screening often includes costly multiple tests without which the ailment often goes undetected. In this backdrop, say doctors, sofosbuvir, is proving to be a magic bullet, unlike some of the alternatives that came with a host of side effects.

"This molecule (Sofosbuvir) is revolutionary. Earlier we used to treat with interferon therapy, but here you have for the first time a therapy in oral form. With this molecule the ease of treatment has improved," said Dr. Mandar Kubal, Director of Mumbai based Infectious Diseases & Pulmonary Care.

Sofosbuvir is costly - in the US, the 400 mg tablet costs $84,000 (nearly Rs 56 lakh) for a 12-week treatment. Gilead, which owns the patent for the molecule in the US and sells it under the brand name Sovaldi, has voluntarily licensed the drug to nearly a dozen Indian companies for a royalty fee. This has made sofosbuvir much cheaper here and the model has been lauded as one that balances innovation with affordability by even the biggest critics of Big Pharma's drug pricing strategies.

A spate of generic launches by the local rights holders over the past eight months has increased the availability of the product and unleashed a fierce marketing war. The companies which expected a jackpot from the drug have not been able to derive the benefits yet. But given that the market itself is evolving, experts believe companies may be in it for the long haul.

"The market is competitive, because a lot of people have launched the drug, but we have done a little bit of innovation because of the chronic nature of the medicine and the cost," said GV Prasad, Chief Executive of Dr. Reddy's Laboratories, a local licence holder. "We are experimenting with the EMI system of financing."

The company has tied up with Mumbai based Arogya Finance for the EMI scheme. It enables patients to pay for the drugs - Rs 96,000 for six months, including tests - in 24 months with 12 per cent interest.

Patients are given coupons to purchase the drug and not cash. This is to ensure that the loan amount is not diverted or misused. However, the biggest challenge for drug companies is not selling their drugs, but identifying the patients who need it. A research report by consultancy firm Decision Resource Group showed that in 2011, only 1 per cent of Hepatitis C patients were treated in India, when the number of people suffering from the disease was about 15 million.

"Hep C is under diagnosed in India, because the high cost of diagnosis deters patients," said DrKubal of Infectious Diseases & Pulmonary Care.Diagnosis includes three tests, which put together cost around Rs 15,000. So, companies like Natco Pharma, another licence holder for Gilead's drug, are attempting to offer heavy discounts, of up to 50 per cent, on diagnosis, said people in the know. Natco did not respond to an email seeking comment.

Zydus Cadila's Sovi Hep is the leading generic Sofosbuvir product in India. In a July interview, CEO Pankaj Patel had highlighted the importance of customer service while selling a drug for a complicated disease like Hep C. Although discounts offer relief to the patients, they impact the profit margin of companies that are already scraping the bottom with a downward spiral in the prices. The price, say some market sources, has fallen to as low as Rs 7,000 for a month's treatment from a high of Rs

Public health activists said access to the drug can be expanded if government makes bulk procurements which are in turn offered through public health services. Leena Menghaney, lawyer and activist of the Doctor without Borders, said the Haryana's Jeevan Rekha scheme can be set as an example.

The programme was started by Dr Malhotra, the liver specialist in Rohtak. Under this, 500 patients who are below poverty line are treated free of cost. Another about 1,200 have received subsidised treatment. Screening costs have been waived off. Dr Malhotra expects further reduction in cost once the Haryana government makes bulk purchase through tenders. "Competition brought down the prices of interferon injections, from Rs 4 lakh to Rs 10,000. We believe that this will happen with Sofosbuvir,"

Source: *The Economic Times, 12thSeptember 2015*

Abbott Disputes Regulator's Cough Syrup Test Results

Abbott Healthcare has challenged the West Bengal drug regulator's findings of excessive levels of codeine—a narcotic substance—in its cough syrup Phensedyl, seeking more details of testing methods, source and the trade channel from where the suspect sample of the medication was picked up. Drug regulators in West Bengal and Himachal Pradesh have charged the company's largest selling brand Phensedyl of containing excessive levels of a codeine, making the US-based Abbott the second multinational in recent months after food major Nestle to confront authorities.

Phensedyl is valued around Rs 250 crore (MAT August 2015, AIOCD Awacs), and is around 3% of Abbott's overall sales of $1 billion in the country. It is the seventh largest top-selling medicine in the domestic retail market. Even with overall sales of just a billion, India is among the five top markets for the MNC. The company has also written to the Drug

TOP 10 SELLING DRUGS IN INDIA

Drug	Company	MAT Value* (₹cr)
Mixtard	Novo Nordisk India	450
Augmentin	GSK Pharma	330
Glycomet GP	USV	314
Monocef	Aristo	281
Corex	Pfizer	262
Becosules	Pfizer	258
Phensedyl Cough Linctus	**Abbott**	**247**
Lantus	Sanofi India	241
Janumet	MSD Pharma	236
Spasmo Proxyvon Plus	Wockhardt	234
Total size of Indian pharmaceutical market		**92,306**

*Till Aug 2015, MAT: Moving Annual Total Source: AIOCD-Awacs

Controller General about the issue, but till now there has been no "official response'' to its communication, an Abbott spokesperson said.

Efforts by TOI to reach the DCGI proved futile. What makes the case complex is that there have been several instances of counterfeit versions of the cough syrup being sold earlier.

Excessive quantity of codeine, an opium derivative, violates drug laws. In March, the drug regulator in Himachal Pradesh, where the syrup is manufactured, sent a "show-cause" notice to the company. The suspect sample which contained a higher level of codeine in the syrup was picked up and tested in West Bengal, with the drug regulator alerting its counterpart in Himachal Pradesh. Since codeine is a narcotic, its supply to companies is also controlled under law. The particular batch of 80,000 bottles was manufactured at Baddi (HP) in February last year, while the show-cause notice was served to the company only in April this year.

The company does not feel the need for a recall of the syrup now as sales of the entire batch started in 2014 itself. Abbott said it had found nothing unusual in its own and third party testing of a retained "control sample" from the same batch of Phensedyl.

"As soon as Abbott received information about the suspect sample, we tested a retained sample both in-house using our own method of analysis, as well as by an accredited independent laboratory. Results of both tests found that the retained sample complied with the required specifications and standards, including the codeine content. We therefore remain confident in the quality of our product," the company spokesperson said. It is not known whether the sample of Phensedyl was a genuine product or a fake one, as it is understood to have been picked up from near the border in West Bengal. Over the years, there have been several instances of cough syrups like Phensedyl and Corex being misused as they contain codeine, which gives a "high".

Recently, the company was reportedly in the dock in Hyderabad for smuggling Rs 57.6 crore worth cough syrup containing narcotic components into Bangladesh using fake bills.

"Abbott has requested the State Drug Controller to provide more information about the source of the suspect sample and the manner in which it was collected, to establish whether the sample was collected from genuine trade channels through proper process under the Drugs and Cosmetics Act", the company official added.

This latest case of Abbott exposes the cracks in India's unwieldy and poorly-resourced drug and food regulatory system, where quality is rarely monitored, creating a potential risk to consumers.

Even the distribution system is not proper, leading to adulteration in many pills, insulins and vaccines in the absence of a cooling chain.

In May this year, the Uttar Pradesh Food Safety and Drug Administration had asked Nestle India to withdraw a batch of popular Maggi noodles from the market after it was reportedly found to contain high levels of lead. A controversy erupted with conflicting reports from state food regulators, leading to Maggi being taken off the shelves and prompting several states to ban the 'two-minute' noodles.

Source: *The Times of India, 15th September 2015*

Glenmark'sNovel Antibody to Enter Clinical Trials

Glenmark Pharmaceuticals has completed the pre-clinical evaluation for its novel bi-specific antibody GBR 1302 and filed the phase I trial application for the same with German regulatory authorities.

Glenmark Pharmaceuticals SA, a wholly-owned subsidiary of the company, has submitted a clinical trial application for GBR 1302 to the Paul-Ehrlich Institute in Germany, Glenmark Pharmaceuticals said in a statement.

GBR 1302 has the potential to be used in the treatment of a broad array of cancers, including breast cancer, and the company expects to obtain approval for the initiation of clinical studies during this financial year, it added.

"During the pre-clinical characterisation of the bi-specific antibody, we have discovered that GBR 1302 does not only kill trastuzumab resistant cancer cells, but also very efficiently kills cancer cells with a weak expression of HER2.," Glenmark Pharmaceuticals Chief Scientific Officer & President — Biologics Michael Buschle said. GBR 1302 material for phase I clinical trials is manufactured at the Glenmark GMP production unit in Switzerland. The stock of Glenmark closed at Rs.1,016.30 on BSE, down 1.40 per cent on Tuesday.

Source: *The Hindu, 16th September 2015*

Sun Pharma Bids Rs300 Crore for US Eye Care Firm Insite Vision

Sun Pharmaceutical Industries, controlled by billionaire Dilip Shanghvi, has bid to acquire US eye care company Insite Vision to expand its basket of specialty products and boost sales, a person familiar with the proposal said.

The deal may be valued at about Rs 300 crore, representing $0.35 for each Insite Vision share.

Insite's revenue stood at close to Rs 55 crore in 2014.

Sun Pharma's bid is higher than an offer for insite Vision made by Canadian drug maker QLT. In August, Iniste Vision announced a definitive agreement with QLT, which pegged its value in a band of $0.25 and $0.30 per share.

Insite Vision said in September 4 disclosure to the stock exchanges that it received an unsolicited offer from a global pharmaceutical company that constituted a "company superior proposal: Insite also said it would be required to pay a $2,667,000 fee to QLT it it terminates their merger agreement.

According to the Insite Vision disclosure, the unidentified bidder has agreed to pay the charges if discussions with QLT do not reach a conclusive end. The last date for the "Negotiation period" was September 10, which analysts said paves the way for Sun Pharma to step in and acquire the firm. Sun Pharma said in a statement it does not comment on market speculation. Insite Vision did not respond to queries till the time of going to press.

Insite Vision is a developer of speciality ophthalmology drugs and has pipeline of eight clinical candidates in various stages. Its marketed productsw include Azasite, an antibiotic azithromycin used for bacterial conjuctivities, and Besivance, an antibiotic for eye infections. Reports suggest the company expects new drug approvals from the US Food and Drug Administration for two drugs – BromSite and DexaSite – in the medium term.

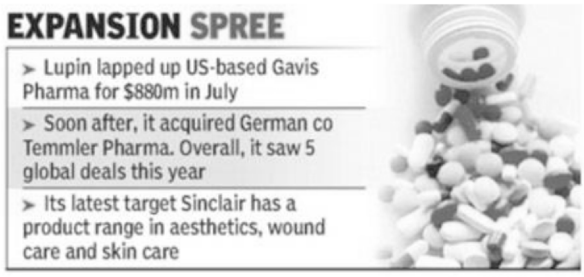
Shanghvi has been keen on expanding the ophthalmic segment for which inorganic route is more viable, "said an analyst from an Indian brokerage. Sun Pharma has consecutively struck global deals that reflect its intentions to ensure sustainable revenue for branded or differentiated drugs.

In March, the company said it acquired GlaxoSmithKline's opiates business in Australia for a undisclosed amount.

Source: *The Economic Times, 16th September 2015*

Lupin Eyes UK Pharma Co Sinclair

Lupin, India's third-largest drug maker by sales, is said to have thrown its hat into the ring to acquire London-listed Sinclair IS Pharma in a deal topping $500 million, people familiar with the matter said. The skin-focused pharma company, owned by a group of private equity investors, has asked investment bank NM Rothschild to help find a buyer for all or part of its business.



Billionaire Desh Bandhu Gupta-controlled Lupin and other Indian peers have been chasing acquisitions to scale up growth in speciality generic drugs, which are used for treating niche diseases, as they have better pricing power. Lupin has been the most positive Indian pharma company active Indian pharma company in terms of overseas acquisitions, having struck five transactions this year, according to M&A data tracker Dealogic. In July, Lupin acquired US-based Gavis Pharmaceuticals for $880 million, the second-biggest overseas deal by an Indian company, giving it access to a portfolio of dermatology drugs. A few days later, it snapped up Germany's Temmler Pharma, which has a strong pipeline of key central nervous system products and dermatology products for anti-wart treatment.

Sinclair, with a range of brands in aesthetics, wound care and skin care, has reported sales of $115 million, coming mostly from the developed markets, which could fit in Lupin's sharp focus on these regions, one of the sources said. If the Sinclair deal materialises, it will boost the Mumbai-based company's presence in Europe, which contributes less than 3 per cent to the pharma giant's sales. The US accounted for 50 per cent of its Rs 12,600-crore sales in fiscal 2015, followed by India at 24 per cent.

Queries mailed to Lupin and Sinclair remained unanswered at the time of going to press. A Lupin spokesperson said that they will get back if they have anything to share.

Shares of Lupin closed at Rs 1845 on the BSE on Wednesday, giving it a market capitalization of Rs 83,037 crore. Lupin has a debt of over Rs 4000 crore post the Gavis buyout and if the Sinclair deal fructifies, it will have to raise funds to finance the acquisition which would further increase its debt , but it will still have a comfortable debt- equity ratio of 0.8 up from 0.4 now, a Pharma analyst said.

Source: *The Times of India, 17th September 2015*

Big Price Increase for TB Drug Set Aside After Outrage

A huge overnight price increase for an important tuberculosis drug has been rescinded after the company that acquired the drug gave it back to its previous owner under pressure, it was announced Monday.

However, outrage over a gigantic price increase for another drug spread into the political sphere on Monday, causing biotechnology stocks to fall broadly as investors worried about possible government action to control pharmaceutical prices. The The Nasdaq Biotechnology Index fell more than 4 per cent.

"Price-gouging like this in the specialty drug market is outrageous," Hillary Rodham Clinton, a contender for the Democratic presidential nomination, said in a tweet on Monday. She said

she would announce a plan on Tuesday to deal with rising drug prices.

Clinton was referring to the actions of Turing Pharmaceuticals, which last month acquired Daraprim, a 62-year-old drug used to treat a serious parasitic infection, and . and raised its price to $750 per tablet, from $13.50.

The cases of Daraprim and of the tuberculosis drug, cycloserine, are examples of a relatively new business strategy — acquiring old, neglected drugs, often for rare diseases, and turning them into costly "specialty" drugs.

CYCLOSERINE & RODELIS

Cycloserine was acquired last month by Rodelis Therapeutics, which promptly raised the price to $10,800 for 30 capsules, from $500. But the company agreed to return the drug to its former owner, a non-profit organisation affiliated with Purdue University, the organisation said on Monday.

"We discovered literally on Thursday the strategy that had been undertaken" by Rodelis, said Dan Hasler, the president of the Purdue Research Foundation which has oversight of the manufacturing operation. "We said this was not what we had intended."

By Saturday, he said, Rodelis had agreed to give back the drug. Rodelis confirmed this in a brief statement on its website.

The foundation now will charge $1,050 for 30 capsules, twice what it charged before, but far less than Rodelis was charging. Hasler said the new price was needed to stem losses.

Cycloserine is used to treat multidrug-resistant tuberculosis, a serious form of the disease that does not respond to the usual drugs. There are only about 90 new cases a year in the US, Hasler said, and about half those patients get treated with cycloserine.

DARAPRIM & TURING PHARMA

Turing does not appear ready to surrender. Turing's founder and chief executive, Martin Shkreli, a former hedge fund manager, used television interviews as well as Twitter and Reddit to defend his move.

He said that toxoplasmosis, the infection Daraprim is used to treat, had been ignored by the pharmaceutical industry because there was little money to be made. Now that Turing can presumably make money, he said, it will be able to educate doctors about the disease, improve delivery to patients and develop better drugs for the infection.

Infectious disease specialists, who have protested the price increase, question the need for new drugs for toxoplasmosis and say that if Turing wants to develop such druch drugs, it should use money from investors. They say the price increase will raise the cost of treating some adult patients with toxoplasmosis to hundreds of thousands of dollars a year.

POLITICAL INTERVENTION

Senator Bernie Sanders of Vermont, who is also vying for the Democratic presidential nomination, sent Turing a letter on Monday demanding information on the price increase.

"Without fast access to this drug, used to treat a very serious parasit ic infection, patients may experience organ failure, blindness or death," Sanders said in a written statement issued with Rep. Elijah Cummings, D-Md. The two lawmakers have been investigating sharp price increases in drugs, many of them old generics.

SALE STRATEGIES

Rodelis, which increased the price of the tuberculosis drug, said last week it needed to invest to make sure the supply of the drug remained

reliable. Rodelis reveals almost no information about itself, such as the names of its executives, directors or investors, on its Web page.

Cycloserine, which went on sale in 1955 and is also known by the brand name Seromycin, was long produced by Eli Lilly, which around 2000 decided to drop the drug, in part because the company was getting out of antibiotics.

Starting in 2003, as part of a philanthropic initiative on TB, Lilly transferred rights and manufacturing skill to generic drug companies in India, China, South Africa and elsewhere to supply the regions most affected. In 2007 it gave the rights for the United States and Canada to the Chao Center for Industrial Pharmacy and Contract Manufacturing, which is under the auspices of the Purdue Research Foundation. The drug made by generic companies abroad costs only about $20 for 100 capsules.

Source: *The Economic Times, 23rd September 2015*

India to Supply Generic Cancer Drug to US

India has agreed to supply to the US generic cancer drugs at a time there is outrage in America about the predatory practices by the US pharma industry, one of whose leaders is getting hammered for increasing the price of life-saving drugs by as much as 5000% overnight. Martin Shkreli, CEO of Turing Pharmaceuticals, is being dubbed the "poster child for price gouging in the pharma industry" and BBC has asked if he is the "the most hated man in America" after he bumped up the price of Daraprim, a drug used to treat a parasitic disease, from an already high $ 13.50 a pill to $750. Daily Beast called him an "asshole".

Although Turing has walked back from the price rise in the face of public anger, his actions have drawn attention to the strategy adopted by Big Pharma to buy out older drugs that are nearing patent loss and hike their price massively, with the argument that the money is needed to fund new research.

On Tuesday, Hillary Clinton stepped up to the plate, offering proposals to control drug prices, even as her challenger Bernie Sanders and others have called for eliminating corporate restrictions on generics. Such a move will help both American patients and Indian drug manufacturers, who have constrained by Big Pharma with the familiar argument that it needs to recoup money spent on research, and generic ma kers profit from the work of Big Pharma.

The full details of the US-India agreement was not disclosed, but Indian officials confirmed that New Delhi had agreed to supply an "off patent" cancer drug.

Such a move could be a template for the supply of life-saving pharmaceuticals to a US system that is overpriced and overburdened, causing untold suffering to millions of poor and middle-class Americans.

The pharma lobby is the biggest contributor of money to the US political systems and it is widely believed that many lawmakers are beholden to it in lieu of campaign contributions. India is the second largest exporter of drugs to the United States. In 2014, India held 13% share of the total 64,170 imported lines of pharmaceuticals, according to a US fact sheet. The US spends close to $ 3 trillion - some 17% of its GDP -on healthcare, an expense that far exceeds even military spending.

The two countries also agreed to a raft of measures, including creating and growing a cadre of field epidemiologists in India to prevent, detect, and respond to infectious disease threats. The US also pledged to engage with India on traditional medicine, health information systems, and agreed to launch a new COLLABORATION on mental health.

Source: *The Times of India, 24th September 2015*

Can India & America Take Gilead – IPA Model Further ?

Pharma is one area, knowledge-based manufacturing could be another. But this requires a mindset change: US and India seeing themselves less as rivals and more as complementary manufacturers

As Prime Minister NarendraModi begins his second trip to the United States, the bilateral relationship between New Delhi and Washington, DC looks remarkably different from the summer of 2014. Modi came to office burdened by the legacy of the UPA government's final months. In the US, India's alleged violation of intellectual property rights (IPR) best practices had become a big issue.

This subject figured in Modi's first visit and early business meetings. At the time, US policy on India had been driven not so much by the White House, the State Department or the Pentagon but by the US Trade Representative's office. Concerns -valid, over-the-top and often a combination -of the US pharmaceutical industry seemed to weigh heavily on diplomacy .

Three actions troubled the pharma lobby: In 2012, the Indian Patent Office granted India's first compulsory licensing order in favour of Natco Pharma, allowing it to manufacture Nexavar, an anti-cancer drug patented by Bayer In 2005, Parliament amended Section 3(d) of the Patents Act and declined to provide intellectual propertypatent protection to incremental changes in drug formulations that did not result in "enhancement of the known efficacy of that substance", a practice that is called "evergreening" In 2013, the Supreme Court refused to grant a patent for Novartis' cancer drug Glivec, citing and upholding Section 3(d) Compulsory licensing is a provision governments can use to ensure mass manufacture of medicines in case of public health emergencies. Many in the government concede the 2012 order did not meet these rigorous benchmarks and was probably unnecessary. However, on Section 3(d) it would appear India is on good ground and the case against "evergreening" is strong.

In the normal course, incorporation of tighter language in India's compulsory licensing rules would have been a reasonable compromise and the matter should have ended there. However, the pharma ceutical industry played hardball. It was alarmed that India's interpretations of IPR would be borrowed by other emerging econ omies.

On its part, the government felt drugs and pharmaceuticals made by India's large generics industry were emerging as a genuine threat to Big Pharma and what was afoot was not a principled battle but an old principled battle but an old fashioned trade war. In Washington, DC the embassy lobbied other industries -defence, aerospace-that said they had had no bad experiences with IPR protection in India. The item moved to the back-burner as the Modi government and the Barack Obama administration courted each other, within which India promised to consider its IPR framework afresh. Further, India did not go down the path predicted by paranoiac critics and did not issue more compulsory licences. Overall, the Modi government created a wider constituency in the US, diluting the voice of pharmaceutical companies.

Having said that, basic arguments remained. It is a fact that innovation and drug development can be expensive. Equally, issues of access and healthcare affordability are vital, and are areas where India's generics companies have lent this country a comparative advantage.

Indeed, as global pharmaceutical companies themselves come under pressure in their home countries as to just how expensive cutting-edge, patented medicines can be, in comparison to generics versions, this is becoming a concern

beyond just India. A story that came to prominence recently was of an Australian academic who began suffering from Hepatitis C, his liver reaching a critical precancerous stage, and realised patented medicines down under would cost him $100,000 for a course. He made his way to Chennai and bought generics versions of the same drug for less than $1,000. Completely cured, he is now running a campaign against the high price of patented medicines.

As insurance and healthcare systems in the West come under fiscal pressure, the impetus to expand sources of drug supply -and offer patients the option of imported but cheaper generics -will be felt. In a sense, this is an analogue to medical tourism and procedure outsourcing. Astute companies have realised the old order is untenable. Gilead, the pharmaceutical company at the centre of the Australian example cited above, recently reached an understanding with the Indian Pharmaceutical Alliance (IPA) and Natco Pharma -the Indian generics maker that had won the controversial compulsory licensing order against Bayer three years ago. IPA and Natco withdrew their cases challenging Gilead's patent application in India, following Gilead's decision to license manufacture of its Hepatitis C drug sofosbuvir to 11 Indian companies, including Natco.

What does the deal entail? Indian companies can use Gilead's technology on payment of a royalty. They are free to price the generic drug as they wish and sell it in India and 100 other developing markets. Gilead retains the developed markets (and retains the consumer headache it has in Australia, but that's another story).

How this arrangement pans out remains to be seen, but it is potentially mutually advantageous. It could drive down prices and enhance access for many of he 170 million worldwide who suffer from chronic Hep C and for the 100,000 or so who die in India each year. For the American pharma company it is a pragmatic recognition that with its manufacturing and logistical costs it alone cannot meet needs of patients in non-First World markets. There is no point setting a price at which there is little affordability and demand. Finally, it is an acknowledgement of how “Make in India“ can result in an India-US win-win.

Frankly, this is where the Gilead-IPA model appears truly attractive. Could it have applicability beyond pharma, in those knowledge-based manufacturing sectors -precision manufacture for instance -where India's technology skills give it an advantage? More than anything else, this requires a mindset change: the US and India seeing themselves less as competitors and more as complementary manufacturers, with the wisdom to segment and divide the international market.

Source: *The Economic Times, 24th September 2015*

Boehringer's Anti-Diabetes Drug May Give it an Edge

The race for the top of India's fast growing anti-diabetes drugs market is heating up, with the Indian arm of German pharmaceutical drug firm Boehringerlgelheim (BI) accelerating its plans to launch Jardiance, its latest bet in a new class of anti-diabetes drugs named SGLT-2 inhibitors (sodium glucose cotransporter 2).

Global firms such as Janssen Pharmaceuticals and Astra Zeneca are ahead with their local launches in the same drug segment, but BI expects an edge with Jardiance in the backdrop of its recently disclosed clinical trial data that demonstrated a clutch of benefits in addition to offering better glucose control against existing compounds.

With Jardiance, BI has the advantage of significantly reducing cardiovascular risks associated with most patients with diabetes. To

date, Jardiance is known to be the only anti-diabetes drug that has showed those benefits although results of clinical trials on similar drugs is awaited over the next two years.

Also, as a class, SGLT-2 compounds have shown significant weight reduction when pitted against older drugs that have often led to weight gain or have remained weight neutral. The long term clinical trial for empagliflozin — known as EMPA REG — was conducted on 7,000 patients, of which a large pool of patients were from India, top company executives told ET.

BI, which has a relatively new presence in India, has seen a strong acceptance for its existing offerings such as Trajenta and Trajenta Duo, two patented drugs that compete against similar brands from Novartis, Merck and Astra Zeneca.

Sharad Tyagi, MD, Boehringer Ingelheim, said the larger aim is to lead the segment and the benefits of Jardiance should see it emerge as a much stronger product in the market.

Tyagi said BI is "looking at seriously evaluating local partnering opportunities closely", but added the thought is more about building the value of the molecule and brand and how the science is presented. BI, for itself, has more than doubled its specialised field force for its anti-diabetes drugs from 160 around two years ago to 400.

A top BI official did not specify the expected price of Jardiance, but added it will be at a steep discount over its international rates and could be seen around the same levels as the existing comparable drugs in India.

AstraZeneca's competing brand Forxiga is available in India for 43 a tablet while Janssen's Invokana is marketed at 51 per tablet.

The Indian market for anti-diabetes products is primarily formed by hundreds of branded generic drugs. The Moving Annual Total for anti-diabetes drugs in India was Rs 7378 crore, as per AIOCD data and growing at over 25%.

An endocrinologist in Mumbai told ET the newly introduced drugs are widely used and are creating a paradigm shift in treatment, but cautioned that their risks and benefits are still being assessed through various global clinical studies.

Source: *The Economic Times, 28th September 2015*

How Dr Reddy's Is Rebooting its Biosimilars Play

When the multi-billion dollar biosimilars opportunity started opening up for Indian pharma companies sometime in 2005, Dr Reddy's was among the first to race off the blocks with four launches in India about as many years. But things have slowed since.

The company's last big biosimilar launch was back in 2011 when it introduced cut-price versions of pegfilgrastim, branded Cresp, a chemotherapy drug used to boost white blood cells. In the meantime, rivals such as Biocon, Cipla, Zydus Cadila and Ahmedabad-based Intas are pressing ahead with multiple launches here.

But contrary to the obvious inference, Dr Reddy's is not slowing its biosimilars push. It is actually holding back a few punches in India, in order to make a bigger and stronger global play in the coming years. Officials at the company say they have strategically compromised speed to market in India, to focus energies for approvals across key regulated and emerging markets, a significant shift from its previous piecemeal approach. The upshot? The addressable market goes up by several billions of dollars.

To the uninitiated, while most drugs are chemicals, another category called biologics is increasingly

emerging as treatments for diseases such as cancer, diabtetes etc. Simply put, biologics are drugs that are based on living cells. And just like generics are copies of chemical drugs, biosimilars are copies of biologics. But biosimilars are very complex proteins. If building a generic copy of a chemical drug is like building a bicycle, building a biosimilar copy of a biologic is comparable to building a Formula One racing car. The costs, therefore, go up sharply.

A generic copycat of a chemical drug may cost $1 million to $5 million depending on its structure, according to experts. For biosimilars that could be up to $100 million to $200 million for the highly regulated markets like Europe or the US. Naturally, biosimilars offer much higher profitability margins and leads to better stock market valuations. "Biosimilars is part of our global transformation into a specialty drug fi rm," says Satish Reddy, chairman, Dr Reddy's Labs. "Investments made over several years (in biosimilars) is coming to fruition now," he adds, referring to the delays mentioned earlier. "The (global) opportunity is tremendous."

According to disclosures, Dr Reddy's is moving steadily in developing a pipeline of late-stage products. While it has already launched drugs like rituximab, pegfilgrastim, darbepoetin, the company's scientists led byCartikeya Reddy who was formerly with Genentech, are working on a few other drugs like trastuzumab, used to treat breast cancer and bevacizumab, for multiple cancers and targeted at emerging and developed markets.

Worth the Wait

The company has also brought under evaluation ten more molecules in the pre-development stage. The cumulative market size for those, according to an investor update by the company in May, could be $37 billion. The key products in that list includes adalimumab, cetuximab, infliximab, ustekinumab, tocilizumab, denosumab, aflibercept and pertuzumab, abatacept and omalizumab — all big moneyspinners. A report byPhillip Capital in May said Dr Reddy's expects 50 fi lings of its fi rst set of six biosimilar drugs across 14 major countries by 2020. "It forecasts incremental sales of $150 200 million from biosimilars in 2020 that will have a margin profi le of over 25%. It also expects licensing/royalty incomes from US and EU by 2020," the report added.

The experience of Dr Reddy's so far has been encouraging. In India, it leads in rituximab and sales are steadily climbing from drugs like fi lgrastim, peg-GCSF and darbepoetin. The market size for the existing portfolio could be as much $3 billion in emerging markets and $25 billion in developed markets. Experts agree that in the world of biosimilars, elaborate global plans for a portfolio of future fi lings is a better strategy than approaching individual markets separately.

"For countries with evolving regulatory pathways and guidelines, companies need to be aware of where they currently are in the cycle, and then anticipate likely future scenarios," says Charu Manaktala, senior director and head of clinical strategy, strategy development-Asia at Quintiles, a global fi rm with functions ranging from clinical research to quality manufacturing consulting. The company's long pause in biosimilar launches seems to be paying off now. Early this month, Novartis' generic arm Sandoz announced the launch of its fi rst ever biosimilars in the US. Branded Zarxio, a biosimilar to Amgen's white blood cellboosting drug Neupogen, hit the market at a 15% discount to the original drug.

Compared with the thinning margins in generic drugs, higher profitability in biosimilars is seen as a great opportunity to differentiate out of the generics rat race. A recent Reuters news report quoted analysts estimating about $110 billion of revenues shifting from innovators to the makers of biosimilars.

But even a few months ago, it seemed as if Dr Reddy's patience was turning out to be costly as rivals furiously pushed biosimilars in India. Intas, which currently markets over nine biosimilars in India, recently upped the game with introduction of copies of Novartis' Lucentis (ranibizumab) - the fi rst such globally - used to treat age-related macular degeneration. Last December, Zydus Cadila, in another first, launched copies of Humira (adalimumab), Abb Vie's blockbuster biologic used extensively on patients suffering from rheumatoid arthritis. Mumbai-based generic giant Cipla is not far on the biosimilars curve, having introduced its darbepoetinalfa last year, following on its earlier introduction of etanercept, a biologic of Amgen's Enbrel that treats rheumatoid arthritis.

Bangalore-based Biocon, which has high stakes in the segment, claimed a strong uptick in its breast cancer treating biosimilar trastuzumab, as part of partnered programmes with global giant Mylan. Ranbaxy — now a Sun Pharma company — too entered the fray with the launch of copies of J&J's Remicade (infliximab), a product it had licensed from Boston-based startup Epirus Biopharmaceuticals.

Dr Reddy's on the other hand was using this time and its extensive global resource network based in Basel, Princeton and Hyderabad to access technology in cell line, process development and bioanalytical capabilities. Besides, it has gathered deep experience in handling regulatory requirements in the EU and US. In 2012, the company also teamed up with Merck Serono of Germany to beef up its efforts. Officials from both the companies told ET that its cost sharing partnership is progressing as per plans, but industry officials noted the possibility of a few changes to the originally agreed terms.

The Challenges

Dr Reddy's spends $300 million in research every year. Of this, about $40 million will be routed each year towards biosimilars over the next five years. High as it may seem, the spending is actually relatively small by global standards.

Pushing a mature pipeline, of which as many as five are monoclonal antibodies may need more capital infusion compared with what global leaders like Korea's Celltrion invest, an expert in regulatory affairs argued. Multiple reports indicate that depending on the targeted markets, selected product, size of clinical trials and other regulatory mandates of each country — regulated or developing — the cost of development of a biosimilar could range anywhere between $100 and $200 million.

But a Dr Reddy's spokesman said the company is okay with being able to develop its target pipeline of products over the next fi ve years with this budget. Dr Reddy's may have taken a calculated bet for the long haul. But will its patience pay off?

Source: *The Economic Times, 29th September 2015*

Pharma Sector Growth Momentum likely to Remain Strong, says Icra

Growth momentum of the domestic pharmaceuticals sector is likely to sustain in the near to medium term owing to steady demand witnessed across therapy segments, regular new launches and price hikes taken by companies, a report by rating agency Icra has said.

"With steady demand being witnessed across therapy segments, regular new launches and price hikes taken by companies in line with Drug Price Control Order (DPCO) guidelines, we expect growth momentum to sustain in the near-to-medium term," the report said.

The regulatory risk of additional therapy segments being brought under control remain a concern with the National Pharmaceutical Pricing Authority (NPPA) proposing to bring at least 100 more drugs

under control by making corrections to DPCO 2013, Icra said.

After experiencing moderation in the growth momentum in FY14 on back of price cuts and trade related disruptions, growth in the domestic pharmaceutical industry bounced back with the industry registering a growth of 12.9 per cent on MAT basis as of March 2015 and 14.3 per cent as of June 2015.

Much of this recovery has been led by price hikes implemented by companies in their National List of Essential Medicines (NLEM) portfolio,stabilisation of supply related issues and increased market penetration.

In addition, the lifestyle oriented therapy segments have continued to grow steadily, which along with increased focus by companies towards introducing new products and enhancing field force productivity has also contributed to the growth momentum, the report said.

Icra also expects steady growth of pharma sector in US market over the medium term.

Source: *The Economic Times, 5th October 2015*